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Supreme Court, U. S.
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IN THE

Supreme Court of the United States

October Term, 1976

No. .....

INTERNATIONAL RECTIFIER CORPORATION, *et al.*,

Petitioners,

vs.

PFIZER, INC.,

Respondent.

VOLUME II
APPENDIX.

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APPENDIX.

Findings of Fact, Conclusions of Law and Order.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

4-71 Civ. 435 and the following

In Re Coordinated Pretrial Proceedings
In Antibiotic Antitrust Actions

4-73 Civ. 188

PFIZER, INC., *Plaintiff,*

vs.

INTERNATIONAL RECTIFIER CORPORATION, RACHELLE LABORATORIES ITALIA, S.p.A., RACHELLE LABORATORIES, INC., RACHELLE PHARMACEUTICALS INTERNATIONAL, S.A., and USV PHARMACEUTICAL CORPORATION, *Defendants.*

This matter comes before the Court upon defendants' motion for partial summary judgment.

INTRODUCTION

This action was filed by Pfizer, Inc. (Pfizer) on January 11, 1973 against International Rectifier Corporation and its four subsidiaries, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc., Rachelle Pharmaceuticals International, S.A., and Rachelle Laboratories (Philippines), Inc. (collectively the Rectifier Defendants) and USV Pharmaceutical Corporation

(Defendant USV) for alleged infringement of Pfizer's Blackwood, et al., Patent No. 3,200,149 (the Doxycycline Patent). Pfizer seeks damages from the defendants and injunctive relief.

Defendants' answers allege, among other things, that the Doxycycline Patent is invalid and unenforceable because of Pfizer's fraud upon, and inequitable conduct before, the Patent Office.

On January 10, 1973 this action, which was commenced in the United States District Court for the Central District of California (Civil Action No. 73-58-R), was transferred by the Multidistrict Panel pursuant to the provisions of 28 U.S.C. §1047 to this Court for coordinated or consolidated pretrial proceedings with *In Re Coordinated Pretrial Proceedings In Antibiotic Antitrust Actions*, 4-71 Civ. 435 (D. Minn. filed August 1, 1971); six of which actions are now in trial.

Pursuant to a September 28, 1972 order in 4-71 Civ. 435, and a further request for the production of documents by Defendant USV, Pfizer produced many thousands of documents to defendants commencing in mid-1973. In December 1973 Defendant USV initiated the deposition of numerous Pfizer employees.

On May 29, 1974 Defendant USV filed the original motion for partial summary judgment (Original Motion). On February 11, 1975 Defendant USV and the Rectifier Defendants filed a second motion for partial summary judgment which incorporated the grounds set forth in the Original Motion and added grounds thereto (Present Motion). Pfizer has opposed, and the parties have fully briefed, both motions.

The Present Motion is based almost entirely on documents produced by Pfizer and the deposition testimony of Pfizer's employees or agents. Pfizer has submitted numerous affidavits in opposition to the motions. Defendants have submitted one affidavit in support of the Present Motion.

Hearings on the Original Motion, the Present Motion, and on evidentiary matters relating thereto were held on September 11 and 13, and October 10, 1974; and on January 24, 25 and 31, February 1 and April 11, 17, 18 and 21, 1975, after which the matter was submitted,

The Present Motion charges Pfizer with fraud and inequitable conduct in the prosecution of the Doxycycline patent application before the Patent Office and with fraud on this Court. Pfizer denies these charges. Defendants contend and Pfizer denies that there is no genuine issue of any material fact concerning the questions of fraud and inequitable conduct in the prosecution of the Doxycycline Patent application and fraud on the Court.

The Court after having considered the documents, depositions and affidavits of the parties and the briefs and many oral arguments of the parties makes its findings of facts and conclusions of law as stated herein.

The procedure to be utilized will be as follows: Before stating the uncontroverted facts, the Court will set forth the basic principles of law which it will apply. After setting forth the uncontroverted facts in each section the Court will then apply the conclusions of law which necessarily follow from the uncontroverted facts. The Court feels that this format will make it

easier for those unfamiliar with the subject matter or any reviewing judicial body to follow the Court's reasoning and the long and often complicated facts.

The headings set forth in the Findings of Fact, and in the Conclusions of Law, are for convenience only and are not part of the Findings of Fact or Conclusions of Law. The facts set forth in the "Facts Respecting the Chronology of the Prosecution of the Doxycycline Application Before the Patent Office", and "The Facts Respecting Technical Terms and Concepts", are findings of fact.

Finally, since it is often difficult to completely separate findings of fact from conclusions of law each is intended to include the other where appropriate.

APPLICABLE PRINCIPLES OF LAW

The grant of summary judgment is appropriate where there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. Rule 56(c), F.R.Civ.P., provides in part that:

> The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

Rule 56(c) is equally applicable in patent cases. *Proler Steel Corp., Inc. v. Luria Brothers & Co., Inc.*, 417 F.2d 272 (9th Cir. 1969). *See also, In Re Yarn Processing Patent Validity Litigation*, 185 U.S.P.Q. 334 (S.D. Fla. 1975). *Bobertz v. General Motors Corp.* 228 F.2d 94 (6th Cir. 1955) *cert. denied* 352

U.S. 824 (1956). *Technograph Printed Circuits Ltd. v. Methode Electronics, Inc.*, 356 F.2d 442, (7th Cir. 1966) *cert. denied* 384 U.S. 950 (1966). *Research Corporation v. Nasco Industries, Inc.*, 501 F.2d 358 (7th Cir. 1974) *cert. denied* .... U.S. .... (.....).

In *Ballantyne Instruments & Electronics Inc. v. Wagner*, 345 F.2d 671 (6th Cir. 1965), the Court stated:

> The public interest in every patent case requires that suits involving the validity of patents should be speedily determined. Thus, wherever patent litigation can be expeditiously handled on motions for summary judgment it should be done provided the necessary safeguards to protect the rights of the litigants are observed.
>
> . . . .
>
> When a motion for summary judgment is made and supported as provided in this rule, [56(c)], an adverse party may not rest upon the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If he does not so respond, summary judgment, if appropriate, shall be entered against him. *Id.* at 672.

In determining whether summary judgment is proper the Court may disregard an opposing party's mere formal denials or generalized averments of fact, *Lawhorn v. Atlantic Refining Company*, 299 F.2d 353, 357 (5th Cir. 1962); *Minnesota Mining & Mfg. Co. v. United States Rubber Co.*, 279 F.2d 409 (4th Cir. 1960); *Liberty Leasing Co. Inc. v. Hillsum Sales Corporation*, 380 F.2d 1013 (5th Cir. 1967); *U.S. v. 373.70 Carats Of Cut, Polished, Rough and Cleaved*

Diamonds, 148 F.Supp. 618 (E.D.N.Y. 1957), as the opposing party is required to bring forth specific facts in order to raise a genuine issue of fact. F.R.Civ.P. 56(e); *Bruce Construction Corp. v. United States,* 242 F.2d 873 (5th Cir. 1957); *Saunders v. National Basketball Association,* 348 F.Supp. 649 (N.D. Ill. 1972).

The Court may disregard affidavits containing speculation *Kern v. Tri-State Insurance Company,* 386 F.2d 754 (8th Cir., 1967), or hearsay *Lyon Ford Inc. v. Ford Motor Company,* 342 F.Supp. 1339 (E.D. N.Y., 1971); *Elasky v. Pennsylvania Railroad Company,* 215 F.Supp. 25 (D. Ohio 1962); *Willetts v. General Tel. Directory Co.,* 38 F.R.D. 466 (S.D. N.Y. 1965), or opinions *G.D. Searle & Co. v. Chas. Pfizer & Co.,* 231 F.2d 316 (7th Cir. 1956), or factual and legal conclusions (*Turner v. Lundquist,* 377 F.2d 44 (9th Cir. 1967); *Wagoner v. Mountain Savings & Loan Ass'n,* 311 F.2d 403 (10th Cir., 1962); *Riggs v. British Commonwealth Corporation,* 459 F.2d 449 (10th Cir. 1972)).

Thus, vague inferences contained in affidavits opposing a motion for summary judgment are unavailing. *Burnham Chemical Co. v. Borax Consolidated, Ltd.,* 170 F.2d 569 (9th Cir. 1948); *Bishop v. Shaughnessy,* 119 F.Supp. 62 (N.D. N.Y. 1950). Where the moving party creates inferences in affidavits and documents which are not denied by the opposing party, those inferences which are "properly drawn therefrom . . . may support a motion for summary judgment" *Lundeen v. Cordner,* 356 F.2d 169 (8th Cir. 1966).

The reason for these rules is clear. Where summary judgment is proper the opposing party should not be permitted to defeat summary judgment and put his

opponent to the expense of a trial by beclouding the absence of genuine, uncontroverted issues of material fact with generalizations, vague inferences, opinions, or factual or legal conclusions.

It is the policy of the law, particularly in patent cases to discourage "dilatory court tactics" *Lear Inc. v. Adkins* 395 U.S. 653 (1969). Summary judgment is designed to do precisely that where there is no genuine issue of material fact.

The fact that patent litigation involves technical matters does not foreclose summary judgment. Where there is no need for expert testimony in order for the Court to understand the uncontroverted facts, the Court is fully capable of determining those uncontroverted facts and applying the law thereto. *Bobertz v. General Motors Corp., supra.* In *Research Corporation v. Nasco Industries Inc., supra,* the Court of Appeals, for the Seventh Circuit, in affirming the grant of a motion for summary judgment, stated:

> There is nothing in Rule 56 to forbid the use of summary judgment procedures to determine whether a genuine issue of fact exists concerning the factual foundation for determination of the ultimate issue of law: obviousness. Although care must be exercised to assure that controverted fact issues are not ignored, see *Tee-Pak, Inc. v. St. Regis Paper Co.,* 491 F.2d 1193, (6th Cir. 1974), * * * a suit concerning the validity of a patent over the prior art is not immune from disposition on motion for summary judgment even though, in addition to prior art patents, deposition testimony of the applicant and affidavits are involved, if no genuine issue of material fact is present.

A R, Inc. v. Electro-Voice, Inc., 311 F.2d 508, 511, (7th Cir. 1962). '*Further, it is well settled that, in a proper case, the validity of a patent may be determined by use of summary judgment.*' *Technograph Printed Circuits, Ltd. v. Methode Electronics, Inc.*, 356 F.2d 442, 446, (7th Cir. 1966), *cert. denied* 384 U.S. 950 (1966).... '*Rule 56 applies to patent cases* and is used in those instances where the structure and mode of operation of the accused devise may be readily comprehended by the court and compared with the invention described and claimed in the patent without need of technical explanation by expert witnesses.' *Technograph Printed Circuits, Ltd. v. Methode Electronics, Inc.*, 356 F.2d 442, 447, (7th Cir. 1966) *cert. denied* 384 U.S. 950, (1966). [Emphasis added.] *Id.* at 361-2.

In the present case, there are over 150 uncontroverted facts whch appear from depositions, affidavits and documents. Although this case is complicated by reason of the sheer number of uncontroverted facts; the number of issues presented by those facts; and a change in the substantive law concerning prior art anticipation (35 U.S.C. §102) during the prosecution of the application, the technology necessary for a complete understanding of the uncontroverted facts is not overly difficult.

For example, issues concerning stereochemistry, which are seemingly the most difficult technically, do not require the Court to understand the chemical reactions which produce Doxycycline, and the McCormick 6-deoxy products; or why, in Doxycycline, the methyl

group (CH_3) at the 6-position is "down" and in the McCormick 6-deoxy compound the methyl group (CH_3) at the 6-position is "up". To decide these issues the Court need only understand that the stereochemical drawings depict "down" with a dotted line and "up" with a solid line. None of this is in dispute. Once these simple technical concepts are understood, the remaining uncontroverted facts consist of no more than Pfizer's knowledge, beliefs and uncertainties concerning absolute stereochemistry at the 5- and 6-positions at different points in time during the prosecution of the Doxycycline application and Pfizer's representations to and withholdings from the Patent Office at certain points in time concerning its knowledge, beliefs and uncertainties concerning that stereochemistry.

Thus, on the issues concerning stereochemistry the Court's task is simply to apply the law to the uncontroverted facts.

Summary judgment is proper even where fraud or inequitable conduct is in issue. In 6 *Moore's Federal Practice* 2554 (2nd Ed. 1965), Professor Moore states:

> But in whatever guise the issue of fraud may appear in an action, the general basic principles underlying summary judgment apply and, if they are met, the issue of fraud may be summarily adjudicated.

Summary judgment is also appropriate in cases involving fraud on the Patent Office. In *Farmer Bros. Company v. The Coca-Cola Company*, 384 F.Supp. 595 (C.D. Cal. 1974), the Court granted summary judgment declaring a patent unenforceable because the patent owner had practiced a fraud on the Patent Office.

The Court held that

> The patentees' failure to be candid with and to make a full and fair disclosure to the Patent Office of all facts relating to . . . their alleged invention constitutes a breach of their duty to the Patent Office and thus renders the Farmer Brothers' patent void and unenforceable.

See also, Proler Steel Corp. v. Luria Bros. & Co., 417 F.2d 272, 273-4 (9th Cir. 1969); *Ashcroft v. Papermate Mfg. Co.*, 434 F.2d 910, 911 (9th Cir., 1970).

A patent applicant has an uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all facts which may be relevant to an issue of patentability. The Courts have found anything less to be fraudulent or inequitable conduct in procuring patent rights. In *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), *rehearing denied.* 325 U.S. 893 (1944), the Supreme Court stated

> Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an *uncompromising duty* to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. . . . This duty is not excused by reasonable doubts as to the sufficiency of the proof of the inequitable conduct nor by resort to independent legal advice. *Id.* at 818.

In applying an applicant's duty of absolute candor and full and complete disclosure, the Court of Appeals for the Sixth Circuit has directed that

> The Patent Office, not having testing facilities of its own, must rely upon information furnished by applicants and their attorneys. Pfizer and Cyanamid, like all other applicants, stood before the Patent Office in a confidential relationship and owed the obligation of frank and truthful disclosure. *Charles Pfizer & Co., Inc. v. FTC*, 401 F.2d 574, 579 (6th Cir. 1968), *cert. denied* 394 U.S. 920 (1969).

Because of the public interest considerations underlying the doctrine of absolute candor and full and complete disclosure before the Patent Office, it is not necessary to establish all of the elements of strict common law fraud. An Applicant commits "Fraud on the Patent Office" if he violates his uncompromising duty of absolute candor and full and complete disclosure.

A strict fiduciary duty is imposed on patent applicants which is analogous to that of a seller of securities or any other person who alone has possession of facts bearing on the public interest. *Monsanto Company v. Rohm & Haas Company*, 312 F.Supp. 778 (E.D. Pa. 1970), *aff'd* 456 F.2d 592 (3rd Cir. 1972), *cert. denied* 407 U.S. 934 (1972).

In *S.E.C. v. Capital Gains Research Bureau*, 375 U.S. 180 (1964), the Supreme Court stated in an analogous fraud case that a breach of the duty of complete disclosure constitutes inequitable conduct and that it is not necessary to establish a specific subjective intent to defraud in order to obtain equitable relief.

Nor is specific subjective intent a prerequisite to finding fraudulent or inequitable conduct before the Patent Office. In *Monolith Portland Midwest Com-*

pany v. Kaiser Aluminum & Chemical Corporation, 407 F.2d 288 (9th Cir. 1969), the patentee argued "that it believed in good faith" that the prior art did not anticipate its claims. The Court stated at page 295 that:

> Whatever theory Monolith may have had in mind about the legal effect of . . . [the prior art], it failed to disclose openly and fully the underlying facts to the Patent Office. At the least, Monolith knew that those facts *might* affect the patentability of the invention.

Similarly, the specific subjective intent of the patentee was considered immaterial in *Monsanto Company v. Rohm & Haas Company, supra:*

> We have concluded that the decisions of the Supreme Court require the highest degree of scientific candor on the part of patent applicants in their dealings with the patent office. *We believe this standard forbids not only the affirmative making of false statements of material fact, but also the suppression of facts known to the applicant which are inconsistent with statements made by the applicant in pursuit of a patent. Id.* at 739.
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> . . . .
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> . . . *[W]e hold that even if Monsanto did not intend to deceive the Patent Office, the fact that it intentionally withheld facts which were material to the decision whether it was entitled to a patent is sufficient to bar the issuance of a patent to it. . . . We believe that all questions of materiality in dealings with the Patent Office ought to be resolved in favor of disclosure.* Only such a standard can protect the public from the

> deadening competitive effect of improvidently issued patents. [Emphasis added.] *Id.* at 799. See also *Robbins Company v. Lawrence Manufacturing Company,* 482 F.2d 426 (9th Cir. 1973).

Thus, Pfizer's assertions of good faith belief, based on its scientists', patent agents' and attorneys' subjective state of mind, in misrepresenting to and withholding relevant facts from the Patent Office does not create any genuine issue of material fact. Therefore, the good faith belief assertions set forth in the majority of the affidavits filed by Pfizer in opposition to the motion have been excluded from the findings of material uncontroverted facts. See also *United States v. Paul Hardeman, Inc., et al.,* 320 F.2d 115 (5th Cir. 1963); and *Robbins v. Gould,* 278 F.2d 116 (5th Cir. 1960).

The requirement of absolute candor and full and complete disclosure in prosecuting patent applications precludes the withholding of "material" prior art, facts and beliefs from, as well as the affirmative misrepresentation of "material" prior art, facts and beliefs to, the Patent Office. *Beckman Instruments, Inc. v. Chemtronics, Inc.,* 428 F.2d 555 (5th Cir. 1970); *Monsanto Company v. Rohm & Haas Company, supra.*

Thus the Court held in *Buzzelli v. Minnesota Mining & Mfg. Co.,* ..... F.Supp. ....., 182 U.S.P.Q. 307 (E.D. Mich. 1974) that an applicant's failure to cite to the Patent Office "the prior art most material and relevant to the subject matter claimed" renders the patent invalid and unenforceable.

Similarly, the Court stated in *Union Carbide Corp. v. Filtrol Corp.,* 357 F.Supp. 37 (C.D. Cal. 1971):

> A patent applicant's duty of disclosure to the Patent Office extends to prior art or facts known to him which would . . . have prevented the patent from issuing or would have restricted the scope of the claims.

"Materiality" under *Beckman* and *Monsanto, supra,* does not require that the patent would not have issued as a matter of law "but for" the misrepresentation or concealment, but only that the misrepresesntation or withholding be relevant to an issue of patentability. *Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F.Supp. 461 (D. Del. 1966), *rev'd on other grounds,* 374 F.2d 473 (3rd Cir. 1967), *cert. denied,* 389 U.S. 826 (1967); *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chemical Corp., supra; SCM Corp. v. Radio Corporation of America,* 318 F.Supp. 433 (S.D. N.Y. 1970); *CPC International, Inc. v. Standard Brands Inc.,* ..... F.Supp. ....., 184 U.S.P.Q. 332 (D. Del. 1974); *United States Movidyn Corp. v. Hercules Incorporated,* 388 F.Supp. 1146 (D. Minn. 1975).

In most of these cases the testimony of the Examiner was unavailable; thus, the Courts have adopted the rule that even if the applicant misrepresents or withholds facts which are not material in a "but for" sense, the Courts will refuse to enforce the patent if the applicant has misrepresented to the Patent Office facts which may be relevant to an issue of patentability.

In this case the parties have submitted three affidavits of Examiner Adams but no affidavits or deposition testimony from the other two Examiners before whom the Doxycycline Patent was prosecuted. Thus, the record shows what Examiner Adams would have done

had he known certain facts misrepresented to or withheld from him, but does not show what the other two Examiners would have done if similarly apprised. Consequently, in applying the rule of the cases cited, *supra,* the Court will consider material, or, relevant, the facts which Examiner Adams would have been interested in and considered relevant to an issue of patentability.

Otherwise stated, the Court will not substitute its judgment for Examiner Adams' judgment in determining relevance to an issue of patentability or in determining what action Examiner Adams would have taken, whether or not the Court believes Examiner Adams to be right or wrong as a matter of law.

The Court recognizes that there is only one reported decision on the use of an Examiner's testimony, as to what prior art or facts he would have considered relevant to an issue of patentability had he been apprised of them. *Chas. Pfizer & Co. v. FTC, supra.* In that case the Court held that the Examiner's testimony as to what he would have done had certain facts been presented to him, even if based on present interpretation with no independent recollection, is admissible evidence.

If the Examiner does not allow the claims sought, or for that matter any claims, and if the applicant believes that the Examiner is wrong, the applicant's only proper remedy is by appeal. *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 443 (1926).

Any other rule would subvert the patent system and permit applicants to misrepresent or withhold facts which might be relevant to an issue of patentability in order to obtain a patent, and then gamble on whether

or not a Court will at a later date agree that the facts withheld or misrepresented were not as a matter of law relevant to an issue of patentability.

The decision in the first instance must be that of the Patent Office, not the applicant. *Monsanto Co. v. Rohm & Haas Co., supra, Beckman Instruments Inc. v. Chemtronics Inc., supra.*

Although Examiner Adams' affidavits are almost entirely based on hypothetical facts, where those hypothetical facts are in accord with the actual facts misrepresented to or withheld from him, his recollection, or even his speculation (where he cannot separate his recollection of what he would have done from his speculation as to what he would have done had he known all of the true facts) is sufficient.

It is common knowledge that the prosecution of a patent application may take several years, as in this case. It is also common knowledge that patent litigation may arise many years after the patent is granted, as in this case. In these circumstances it is not surprising that an Examiner, who handles many applications at the same time, may not be able to recall with exactitude what he would have done had he known certain facts many years prior to the taking of his testimony. Thus, his present recollection or even his present recollection coupled with his present speculation as to what he would have done is often the best independent evidence available. Any other rule which fails to adopt the Examiner's recollection or the combination of his recollection and speculation would hardly discourage an applicant from misrepresenting or withholding relevant facts. *Chas. Pfizer & Co. v. FTC, supra.*

As to the other two Examiners, since their testimony is not before the Court, it cannot be determined with any certainty what they would have done had they known the true facts during the time they were the Examiners for the Doxycycline application. Therefore, for the time period that they were so acting, the Court will regard as relevant those concealments or misrepresentations which may have been relevant to the statutory criterion for patentability.

In summary, since the testimony of Examiners Berg and Modance is not before the Court, the Court, based on the uncontroverted facts, will determine materiality during the time they were acting on the Doxycycline application in the context of whether any withholding or misrepresentation was relevant to an issue of whether or not Doxycycline was patentable. However, the Court will accept as conclusive Examiner Adams' affidavit testimony concerning relevance during the time he served in the Patent Office as the Examiner on the Doxycycline application. In this regard, were there no testimony from Examiner Adams, the Court would conclude as set forth in Conclusions D, H, J and L that the withholding or misrepresentation of prior art, facts or beliefs was relevant to an issue of whether or not doxycycline was patentable. Thus, in this alternative circumstance, the Court would disagree with Examiner Adams' affidavit testimony only on the issue of Pfizer's false analogy as set forth in Conclusion F between doxycycline and the prior art "epimers"—and on that issue the Court would conclude from the uncontroverted facts that Pfizer's false analogy was material to the issue of whether or not doxycycline was patentable under 35 U.S.C. §103 during the prosecution of the Doxycycline application.

An applicant's duty of absolute candor and full and complete disclosure to the Patent Office would be meaningless were not an applicant obligated to exercise reasonable diligence in discharging that duty. The Courts cannot, therefore, excuse the failure to exercise reasonable diligence in disclosing prior art or facts or beliefs which may be relevant to an issue of patentability, and which are known to the applicant, on the ground that the prior art or facts or beliefs are at some later date rendered moot by changes in the law or by later discovered facts.

An applicant has a duty to report to the Patent Office all facts concerning fraud or inequitable conduct. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., supra.*

In this regard, Patent Office Rule 56 (37 C.F.R. §1.56) provides, in part, that:

> Any application in connection with which any fraud is practiced or attempted on the Patent Office, may be stricken from the files.

The Patent Office Rules are to be broadly applied in the consideration of fraud or inequitable conduct during the prosecution of a patent application. *Norton v. Curtiss,* 433 F.2d 779 (C.C.P.A. 1970).

Cumulative misrepresentation or withholding of prior art or facts during the prosecution of a patent application, if relevant at the time of the misrepresentation or withholding, but which eventually become moot for one reason or another, may evidence a course of calculated reckless conduct as to the disclosure of the true and complete facts, which fails to satisfy an applicant's duty of absolute candor and full and complete disclosure to the Patent Office, and may

be so inequitable as to render the patent unenforceable.

In *Honeywell Inc. v. Sperry Rand Corp.,* .... F. Supp. ...., 180 U.S.P.Q. 673 (D. Minn. 1973), the Court said:

> If the conduct of the applicant is reprehensible it matters not that it was really unnecessary, and the patent is unenforceable.

See also, Monolith Portland Midwest Co. v. Kaiser Aluminum Co., supra; Intermountain Research & Engr. Co. v. Hercules, ... F.Supp. ...., 171 U.S.P.Q. 577, 631 (C.D.Cal. 1971), *aff'd* .... F.2d .... (9th Cir., 1974; appeal Nos. 71-2797, 71-2938).

Although fraud on the Patent Office must be proven by "clear, unequivocal and convincing" evidence, *Schnadig Corporation v. Gaines Manufacturing Co.,* 494 F.2d 383, 392 (6th Cir. 1974), this burden is clearly met where the uncontroverted evidence warrants the grant of a summary judgment as a matter of law.

Fraud or inequitable conduct in obtaining a single claim of a patent renders the entire patent invalid or unenforceable. *Marconi Wireless Telegraph v. United States,* 320 U.S. 1, 57-58 (1943); *Strong v. General Electric Co.,* 305 F.Supp. 1084 (N.D. Ga., 1969), *aff'd* 434 F.2d 1042 (5th Cir. 1960), *cert. denied* 403 U.S. 906 (1970); *Kearney & Trecker Corp. v. Giddings & Lewis, Inc.,* 452 F.2d 579, 596 (7th Cir. 1971), *cert. denied* 405 U.S. 1066 (1972); *Chromalloy American Corp. v. Alloy Surfaces Co.,* 339 F. Supp. 859 (D. Del. 1972); *East Chicago Machine Tool Corp. v. Stone Container Corp.,* .... F.Supp. ...., 181 U.S.P.Q. 744 (ND. Ill. 1974); *Kearney & Trecker*

Corp. v. Cincinnati Milacron, ... F.Supp. ...., 184 U.S.P.Q. 134 (S.D. Ohio 1974).

Oral disclosures to a Patent Examiner, which are not fairly summarized in an amendment filed in the Patent Office, may not be relied upon to satisfy a patent applicant's duty of absolute candor and full and complete disclosure.

Patent Office Rule 2 (37 C.F.R. §1.2) provides that:

> 2. Business to be transacted in writing. *All business with the Patent Office should be transacted in writing.* The personal attendance of applicants or their attorneys or agents at the Patent Office is unnecessary. *The action of the Patent Office will be based exclusively on the written record in the Office.* No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt. [Emphasis added.]

Patent Office Rule 133(b) (37 C.F.R. §1.133(b)) provides that:

> In every instance where reconsideration is requested in view of an interview with an examiner, *a complete written statement* of the reasons presented at the interview as warranting favorable action must be filed by the applicant. . . .

The Patent Office acts on written applications, and written amendments by written rejections made in "official actions" or written notices of allowance. The purpose of Patent Office Rules 2 and 133(b) is to insure that, if a patent is either granted or rejected, all of the reasons are set forth in the file wrapper and contents. The Rules are enacted pursuant to statutory

authority, 35 U.S.C. §6 and, therefore, if not inconsistent with the patent statutes, have the force of law. *Hadco Products, Inc. v. Lighting Corp. of America, Inc.,* 312 F.Supp. 1173 (E.D. Pa. 1970), *Buzzelli v. Minnesota Mining & Mfg. Co., supra.*

The public is entitled to know from a file wrapper and contents each and every fact and argument presented by the applicant and each and every reason why the Examiner rejected or allowed the application. *See, In re Rubinfield,* 270 F.2d 391, (C.C.P.A. 1959); *Sperry Rand Corporation v. Bell Telephone Laboratories, Inc.,* 171 F.Supp. 343 (S.D. N.Y. 1959); *Gearon v. United States,* 121 F.Supp. 652 (Ct. Cl. 1954); *Application of Kaghan et al.,* 387 F.2d 398 (C.C.P.A. 1967); and *Halliburton Co. v. Dow Chemical Co.,* ..... F.Supp. ....., 182 U.S.P.Q. 178 (N.D. Okla. 1974).

Oral disclosure of and discussion of prior art, facts or beliefs with a Patent Examiner in an interview which are not made of record does not satisfy the applicant's absolute duty of full and complete disclosure. *LaMaur v. DeMert and Dougherty,* 265 F.Supp. 961 (N.D. Ill. 1965); *Buzzelli v. Minnesota Mining & Mfg. Co., supra.*

Stated differently, an applicant is estopped to assert that he called prior art, facts or beliefs to the attention of the Patent Examiner where he makes no written record thereof in the formal prosecution record.

Prior art, facts and beliefs which are known to the inventors or to the officers, patent agents or key scientists of a corporate applicant for a patent are imputed to the applicant and his attorneys who prosecute the application as a matter of law. Thus, if any

of these persons misrepresents to, or withholds from, the Patent Office prior art, facts or beliefs which are relevant to an issue of patentability, the patent is invalid and unenforceable. *Chas. Pfizer & Co., Inc. v. FTC, supra; Air Shields Inc. v. Air Reduction Co. Inc.*, 331 F.Supp. 673 (1971), *aff'd* 474 F.2d 1351 (7th Cir. 1973).

Where a patentee in attempting to enforce a patent commits a fraud on the Court, the Court upon the discovery of that fraud, in the inherent exercise of its equitable powers, may hold the patent unenforceable, *Hazel-Atlas Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944). *See also, Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933); and *Mas v. Coca-Cola Co.*, 163 F.2d 505 (4th Cir. 1947).

In *Mas*, the Court stated at page 508:

> Although most cases in which the clean hands doctrine has been applied are cases in which the cause of action itself has arisen out of or been the fruit of unconscionable conduct, we do not understand that it is a pre-requisite to the application of the doctrine that the cause of action shall have so arisen. *It is sufficient to bar relief that plaintiff has been guilty of unconscionable conduct directly related to the cause of action,* such as the fabrication of testimony, the subornation of perjury *or other like attempt to perpetrate a fraud upon the court or take an unconscionable advantage of his adversary.* . . . [Emphasis added.]

35 U.S.C. §285 provides that the Court can award reasonable attorneys fees to the prevailing party in an "exceptional" case whether or not the Court finds that the applicant committed fraud on the Patent Office.

Monolith Portland Midwest Co. v. Kaiser Aluminum & Chemical Corp., supra; C. F. Strassheim Co. v. Gold Medal Furniture Co., 477 F.2d 818 (7th Cir. 1973).

In the *Strassheim* case, *supra,* the Court awarded reasonable attorneys fees because of the patentee's "serious lack of diligence" in representations made in prosecuting the patent application and its "comparable lack of diligence in responding to discovery requests" which the Court characterized as "exceptional oversights" which were "critically important". The Court said:

> We do note, however, that there can be no question about the ready availability of the true facts to defendant's executives and attorney when the patent application was filed. The failure to make an appropriate investigation at that time . . . reflects an extraordinary lack of diligence to which we consider it appropriate to attach legal significance.
>
> Defendant and its trial counsel also displayed a comparable lack of diligence in responding to discovery requests. . . .
>
> . . . .
>
> . . . [P]laintff's counsel requested that certain documents be produced for use at the deposition.
>
> Many other documents were produced . . . but none of the items in question was mentioned or brought to the attention of plaintiff's counsel.

The Court may take judicial notice of the Patent Office rules in effect during the prosecution of the Doxycycline application and the relevant proceedings in the coordinated and consolidated actions. Federal Rules of Evidence, Art. II, Rule 201 subd. (b), (c) and (f).

FINDINGS OF FACTS AND CONCLUSIONS OF LAW

A. The Facts Respecting the Chronology of the Prosecution of the Doxycycline Application Before the Patent Office

1. The Doxycycline Patent was granted on patent application Serial No. 106,146 filed in the names of Robert K. Blackwood, Hans H. Rennhard, John J. Beereboom and Charles R. Stephens as inventors on May 5, 1961 in the United States Patent Office (Doxycycline application) (DX 5).[1] That application was called a "continuation-in-part" of prior application Serial No. 31,236 filed May 23, 1960 (parent application) (DX 5, p. 15).

2. The uncontroverted and material chronology of the Doxycycline application is as follows:

(a) May 5, 1961: Pfizer files the Doxycycline application (DX 5, cover page and pp. 1-56).

(b) October 26, 1961: The First Patent Office Action, by Examiner Adams (DX 5, pp. 58-59).

(c) On or about March 29, 1962: Interview between Pfizer Attorney Nicholas E. Oglesby (Oglesby) and Examiner Adams (Oglesby Affidavit of March 18, 1975; p. 2, paragraphs 12-14).

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[1]The record reference for each uncontroverted fact as found herein is indicated after each numbered finding. "DX" refers to exhibits placed in evidence by Defendants and "PX" refers to exhibits placed in evidence by Plaintiff. ".... Affidavit" refers to the affidavits submitted by the parties. ".... deposition" refers to the depositions which are exhibits to the Original or the Present Motion. "Tr. ...." refers to the transcripts of hearings held before the Court.

(d) April 26, 1962: Pfizer's First Amendment and Supporting English and McBride Affidavits (DX 5, pp. 60-67).

(e) October 30, 1962: The Second Patent Office Action, by Examiner Berg (DX 5, pp. 68-69).

(f) On or about March 6, 1963: Interview between Oglesby and Examiner Berg (Oglesby Affidavit dated March 18, 1975, p. 3, paragraph 15).

(g) April 30, 1963: Pfizer's Second Amendment and Exhibits thereto (DX 5, pp. 69-88).

(h) On or about April 14, 1964: Telephone Interview between Oglesby and Examiner Modance (Oglesby Affidavit dated March 18, 1975, p. 4, paragraph 19).

(i) On or about July 9, 1964: Interview between Oglesby and Examiner Modance (Oglesby Affidavit dated March 18, 1975, p. 4, paragraph 20).

(j) July 23, 1964: Pfizer's Third Amendment (DX 5, pp. 89-90).

(k) November 9, 1964: Pfizer's Fourth Amendment (DX 5, pp. 91-92).

(l) January 19, 1965: Third and Final Patent Office Action, by Examiner Adams (DX 5, pp. 93-96).

(m) February 23, 1965: Interview between Oglesby and Examiner Adams (Oglesby Affidavit dated March 18, 1975, pp. 13-14, paragraph 76).

(n) March 5, 1965: Pfizer's Fifth Amendment (DX 5, pp. 98-108).

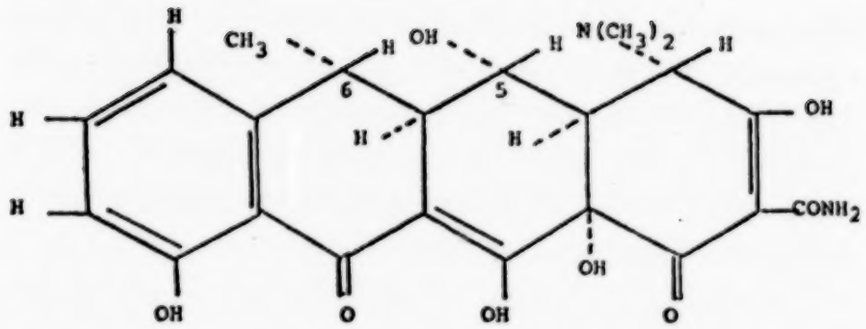
(o) April 9, 1965: Notice of Allowance (DX 5, p. 110).

(p) August 10, 1965: Doxycycline patent issued (DX 67).

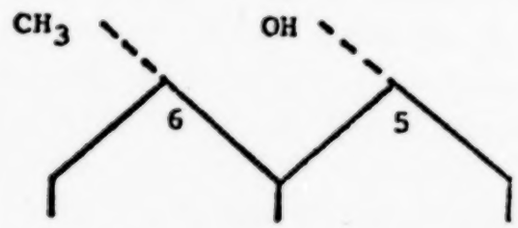
(q) The Doxycycline application was prosecuted by Oglesby who was then and is now a partner in the law firm of Connolly, Bove and Lodge, which firm transacts business before the Patent Office under the name of Connolly & Hutz (Oglesby Affidavit dated July 30, 1974, paragraph 1, page 1; Pfizer Brief dated April 21, 1975, p. 1).

B. The Facts Respecting Technical Terms and Concepts

3. Doxycycline (originally described by Pfizer in the Doxycycline application as "6-epi-6-deoxy-5-oxytetracycline" and later as "∝-6-deoxy-5-oxytetracycline") is a member of the group of tetracycline derivatives known as 6-deoxy-tetracyclines (DX 67). In particular, doxycycline is identical to oxytetracycline (also known as 5-oxytetracycline; Pfizer's trademark for oxytetracycline is "Terramycin") its parent fermentation product except that the hydroxyl (OH) atom group (or substituent) at the "6-position" of the oxytetracycline molecule has been removed and replaced with a hydrogen (H) atom (von Wittenau Affidavit dated March 27, 1975, paragraphs 2 and 9). The stereochemical structure of doxycycline is depicted as follows (von Wittenau Affidavit, paragraph 9):



The stereochemical issues in this case involve only the methyl (CH_3) group at the 6-position and the hydroxyl (OH) group at the 5-position which in the above drawing is depicted as follows:



In the preceding drawing the four connected hexagons are carbon rings and the dotted and solid lines connected to the rings are atom groups (or substituents) which are oriented in the third dimension behind and in front of the plane of the paper. Identifying numbers have been added to designate the 5- and 6-positions in the carbon rings which form the basic tetracycline nucleus. The atom groups (or substituents) connected to the tetracycline nucleus by dotted lines are all on the same side of the molecule. The atom groups (or substituents) connected to the tetracycline nucleus by solid lines are all on the opposite side of the molecule. Thus, at the 5- and 6-positions the solid

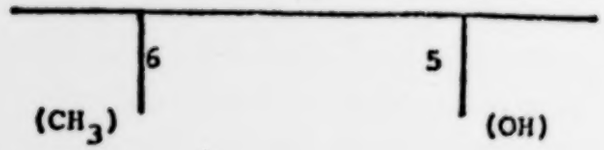
lines showing the bonds to the hydrogen (H) atoms represent the dimension rising out of the paper, *or "up"*, and the dotted lines showing the bonds to the hydroxyl (OH) atom group and the methyl (CH_3) atom group represent the dimension descending below the plane of the paper *or "down"*.

4. The identification of the positions of the atoms or atom groups of a chemical compound in space is called the "stereochemistry" or "stereochemical configuration" of that compound. The identification of the spatial relationship between an atom group at one position on the nucleus and another atom group at a different position on the nucleus of the same compound or at the same position on the nucleus of a different compound is referred to as the relative stereochemical configuration of the two atom groups (Tr. April 11, 1975, pp. 126-31). In other words, the relative configuration of the methyl group (CH_3) at the 6-position and the hydroxyl group (OH) at the 5-position in the Doxycycline molecule is the same, because both of these atom groups are on the same side of the molecule. Knowledge of the relative stereochemical configuration of these two atom groups at these two positions does not teach whether both atom groups are "up" or both are "down", but only that both are on the same side. Similarly, knowledge of the relative stereochemical configuration of two atom groups at the same position does not teach one which atom group is "up" and which atom group is "down", but only that one is "up" and one is "down". (Woodward Affidavit dated June 14, 1974, paragraph 4, page 5).

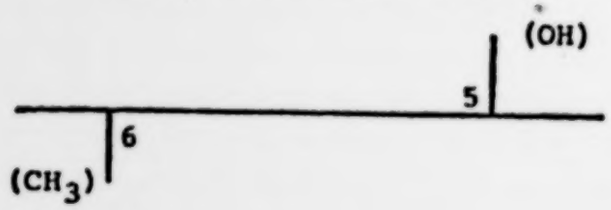
5. The absolute stereochemical configuration of a compound is the precise spatial orientation of the

atom groups at the different positions of the molecule. Thus, knowledge of the absolute stereochemical configuration of Doxycycline tells us that the methyl group (CH_3) at the 6-position is "down", or, below the molecule as described above, whereas the hydrogen atom (H) at the same position is "up", or above the molecule as described above (Tr. April 11, 1975, p. 127).

In "up or down" terms the absolute configuration of the atom groups at the 5- and 6-positions in Doxycycline (the hydroxyl (OH) and methyl (CH_3) groups, respectively), can be depicted in a simplified, non-technical line drawing as follows:



If in Doxycycline the hydroxyl group (OH) was up, the atom groups at the 5- and 6-positions would be depicted in a simple line drawing as follows:



As far as the issues in this case concern stereochemistry there is no dispute concerning the carbon rings or the numbered positions in those carbon rings or the identification of, or orientation of the attached atom groups. The stereochemical issues involve only Pfizer's knowledge, beliefs and uncertainties concerning the spatial orientation of the methyl group at the 6-position and the hydroxyl group at the 5-position

of Doxycycline, at different times during the four year prosecution of the Doxycycline application. (Woodward Affidavit dated June 14, 1974, paragraph 4, page 9).

6. In the tetracycline nucleus there are six different positions (asymmetric centers), including the 5- and 6-positions, at which so-called "epimers" may be formed. At each of these positions the two atom groups attached to the nucleus may be oriented in one of two ways, at the 6-position the methyl (CH_3) can be "down" and the hydrogen (H) "up", or vice versa. One chemical compound may have the methyl "down" and the hydrogen "up", and a different chemical compound may have the methyl "up" and the hydrogen "down". These two compounds which differ from one another only in the orientation of the atom groups at the same position are each known in the art as "epimers", or each is the epimer of the other. (Woodward Affidavit dated June 14, 1974, paragraph 4, pp. 3, 4).

In the art the term "epi" has been used as a prefix to identify the compound having the second configuration, *i.e.*, if a compound with the methyl group "down" is first produced, and the compound with the methyl group in the "up" position is subsequently produced, it is given the "epi" prefix to distinguish it from the first compound produced (Woodward Affidavit dated June 14, 1974, paragraph 4, p. 4).

As a result the term epimer as used in the art does not indicate the absolute stereochemistry of a compound, i.e., the "up-down" configuration of its atom groups. Thus, knowledge that a tetracycline bearing methyl and hydrogen groups at the 6-position is an epimer of another such compound indicates only that the other compound (which may also be an epimer)

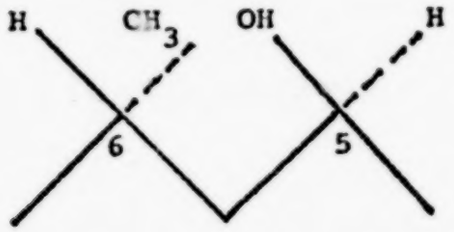
has the same groups oriented in the opposite manner—however, from this information one does not know on which epimer the methyl group is "up" and on which epimer it is "down", but merely that it is "up" on one epimer and "down" on the other epimer.

C. The Facts Respecting Pfizer's Concealment of the Belgian Patent and Its Inability to Distinguish the Belgian Patent

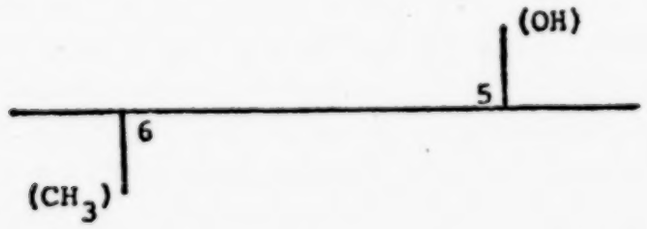
1. The Doxycycline application disclosed a class of epimers of the 6-deoxytetracyclines ("Pfizer's 6-deoxytetracyclines") including both those having a hydroxyl (OH) group at the 5-position, and those having only hydrogen (H) atoms at that position (DX 5, p. 11). As filed, the Doxycycline application claimed only certain of Pfizer's 6-deoxytetracyclines, *i.e.*, those compounds—including doxycycline—having an hydroxyl (or "oxy") group at the 5-position (DX 5, pp. 53-54).

2. Before filing the Doxycycline application Pfizer was aware of Belgian Patent No. 572,584 ("Belgian Patent"), (Frost letter to Oglesby dated March 17, 1961, DX 2, Pfizer Brief dated March 17, 1975, p. 23) which issued to McCormick et al. of American Cyanamid on April 30, 1959 (DX 1, a certified translation is the sole exhibit to the Affidavit of von Wittenau dated March 27, 1975). The Belgian Patent disclosed the preparation of 6-deoxy-5-oxytetracycline (McCormick 6-deoxy compound), by hydrogenation of its parent fermentation produced tetracycline, *i.e.*, oxytetracycline (DX 1, p. 2; Oglesby Affidavit dated July 30, 1974, paragraph 3, p. 2). The Belgian Patent further depicted a stereochemical formula (DX 1, p. 2) purporting to show the absolute stereochemical configuration of the McCormick 6-deoxy compound at

the 5- and 6-positions (Pfizer Brief dated January 3, 1975, pp. 11-12), as follows:



In a simple line drawing, the absolute stereochemical formula for the major atom groups, the methyl (CH_3) and the hydroxyl (OH), at the 6- and 5-positions, respectively, as described in the Belgian Patent appear as follows:



3. At the time the Doxycycline application was filed Pfizer believed that the stereochemical formula described in the Belgian Patent did not correctly depict the absolute stereochemical configuration of the McCormick 6-deoxy compound at the 6-position, Pfizer believed that in the McCormick 6-deoxy compound the methyl group (CH_3) at the 6-position was "up" (DX 2, 3 and 30; Oglesby Affidavit dated March 18, 1975, paragraph 6, p. 2).

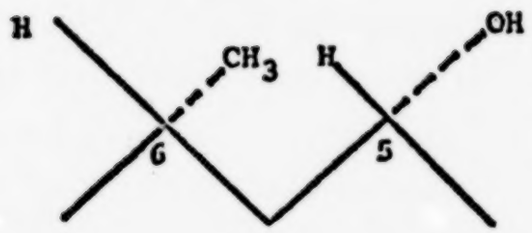
4. At the time the Doxycycline application was filed Pfizer believed that Doxycycline had the opposite absolute stereochemical configuration at the 6-position from the McCormick 6-deoxy compound (Oglesby Affidavit dated March 18, 1975, paragraph 32, p. 2),

Pfizer believed that in Doxycycline the methyl group (CH_3) at the 6-position was "down" (DX 3).

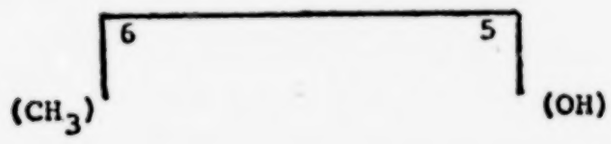
5. At the time the Doxycycline application was filed Pfizer had an uncertain belief that the absolute stereochemical formula in the Belgian Patent did not correctly depict the absolute stereochemical configuration of the McCormick 6-deoxy compound at the 5-position, Pfizer had an uncertain belief that in the McCormick 6-deoxy compound the hydroxyl group (OH) at the 5-position was "down" (DX 3, p. 9 and DX 30; Woodward Affidavit dated June 14, 1974, pp. 7-8; Oglesby Affidavit dated July 30, 1974, paragraph 3, p. 2; Oglesby Affidavit dated March 18, 1975, paragraph 6, p. 2).

6. At the time the Doxycycline application was filed Pfizer had an uncertain belief that Doxycycline had the same absolute stereochemical configuration at the 5-position as the McCormick 6-deoxy compound (Oglesby Affidavit dated March 18, 1975, paragraph 5, p. 2), *i.e.*, Pfizer had an uncertain belief that in both Doxycycline and the McCormick 6-deoxy compound the hydroxyl group (OH) at the 5-position was "down" (DX 3, p. 9; Oglesby deposition of March 6, 1974, pp. 231-2; Pfizer Brief dated August 8, 1974; Tr. September 11, 1974, pp. 131-132; Tr. April 17, 1975, p. 244; Tr. April 21, 1975, pp. 498-499).

7. Pfizer's belief as to the absolute stereochemical configuration of Doxycycline at the 6-position and its uncertain belief as to the absolute stereochemical configuration of Doxycycline at the 5-position was as follows:



In a simple line drawing Pfizer's belief and uncertain belief as to absolute stereochemical formula for the major atom groups at the 5- and 6-positions of Doxycycline was:



8. At the time the Doxycycline application was filed Pfizer knew that Doxycycline had a relative stereochemical configuration in which at the 6-position the methyl group (CH_3) was opposite (or reverse) to the methyl group at the 6-position in the McCormick 6-deoxy compound, and Pfizer believed that Doxycycline had a relative stereochemical configuration in which at the 6-position the methyl group (CH_3) was in the same position as the methyl group at the 6-position in the natural fermentation produced oxytetracycline compound (Woodward Affidavit dated June 14, 1974, paragraph 4, pp. 7-8; Tr. September 11, 1974, p. 129).

9. At the time the Doxycycline application was filed, Pfizer knew that Doxycycline had a relative stereochemical configuration in which at the 5-position the hydroxyl group (OH) was the same as the hydroxyl group in the McCormick 6-deoxy compound and in

the natural fermentation produced oxytetracycline compound (Oglesby Affidavit dated March 18, 1975).

10. At the time the Doxycycline application was filed, and based on its belief as to the absolute stereochemistry of Doxycycline at the 6-position and its uncertain belief as to the absolute stereochemistry of Doxycycline at the 5-position, and its establishment of the relative stereochemistry of Doxycycline at the 6-position, Pfizer understood that the absolute stereochemical formula depicted in the Belgian Patent was equally pertinent prior art, if not more pertinent prior art, than the relative stereochemistry of the McCormick 6-deoxy compound.

11. At the time the Doxycycline application was filed Oglesby understood that it was his duty to bring the most pertinent prior art to the attention of the Patent Office with reasonable diligence (Tr. January 31, 1975, p. 422).

12. At the time the Doxycycline application was filed Oglesby understood that if the absolute stereochemical formula depicted in the Belgian Patent was the most pertinent prior art and if Pfizer had uncertainties as to the absolute stereochemical configuration of Doxycycline at the 5-position, it was his duty to disclose the Belgian Patent and those uncertainties to the Patent Office with reasonable diligence. (Tr. January 31, 1975, pp. 422-425).

13. At the time the Doxycycline application was filed Pfizer did not disclose the Belgian Patent or the absolute stereochemical formula depicted therein to the Patent Office. Rather, in the original specification Pfizer made no mention of the Belgian Patent or its absolute stereochemical formula, but compared Doxy-

cycline only to the relative stereochemistry of "known 6-deoxytetracyclines", that is, the compounds actually produced by the process of the Belgian Patent such as the McCormick 6-deoxy compound, stating that Doxycycline was the reverse of the "known 6-deoxytetracyclines" at the 6-position, thereby indicating relative stereochemistry only (DX 5, p. 1).

14. At the time the Doxycycline application was filed Pfizer believed that the absolute stereochemical configuration of Doxycycline was the same as the absolute stereochemical formula depicted in the Belgian Patent at the 6-position, and had an uncertain belief that the absolute stereochemical configuration of Doxycycline was the opposite of the absolute stereochemical formula depicted in the Belgian Patent at the 5-position.

15. At the time the Doxycycline application was filed Pfizer had not proven its belief that Doxycycline had an absolute stereochemical configuration in which the methyl group (CH_3) at the 6-position was "down" or proven its uncertain belief that in Doxycycline the hydroxyl group (OH) at the 5-position was "down" (Stephens Affidavit dated March 27, 1975, paragraph 6, p. 1; Woodward Affidavit dated June 14, 1974, paragraph 4, p. 4; Pfizer Brief dated May 1, 1974, p. 6; Tr. September 11, 1974, p. 104).

16. At the time the Doxycycline application was filed and until on or about April 24, 1963, Pfizer believed that the "von Bramer Doctrine", *In re von Bramer*, 127 F.2d 149 (C.C.P.A. 1942), precluded the grant of a patent on a chemical compound over a prior art reference which depicted that compound

even though the prior art reference did not enable those having ordinary skill in the art to produce the compound depicted (DX 2; Pfizer Brief dated March 7, 1975, p. 25).

17. At the time the Doxycycline application was filed Pfizer understood that if its belief concerning the absolute stereochemical configuration of Doxycycline at the 6-position was correct the Belgian Patent depicted the absolute stereochemical configuration of Doxycycline at the 6-position and did not depict the McCormick 6-deoxy compound at the 6-position (Oglesby Affidavit dated March 18, 1975, paragraphs 6 and 7, p. 2).

18. At the time the Doxycycline application was filed Pfizer understood that if its uncertain belief concerning the absolute stereochemical configuration of Doxycycline at the 5-position was correct the Belgian Patent did not depict the absolute stereochemical configuration of Doxycycline at the 5-position (Oglesby Affidavit dated March 18, 1975, paragraphs 5 and 6, p. 2), and conversely at the time the Doxycycline application was filed Pfizer understood that if its uncertain belief concerning the absolute stereochemical configuration of Doxycycline at the 5-position was incorrect the Belgian Patent depicted the absolute stereochemical configuration of Doxycycline at the 5-position (Woodward Affidavit dated June 14, 1974, paragraph 4, p. 9).

19. At the time the Doxycycline application was filed Pfizer, in claiming Doxycycline, resolved its uncertain belief concerning the absolute stereochemistry of Doxycycline at the 5-position in its own favor (Tr. April 17, 1975, p. 244).

20. At the time the Doxycycline application was filed, Pfizer believed that the absolute stereochemical formula depicted in the Belgian Patent correctly depicted Pfizer's 6-deoxytetracyclines which did not have a hydroxyl (OH) group at the 5-position but had two hydrogen (H) groups at the 5-position, one "up" and one "down". Since the Belgian Patent described either a hydroxyl (OH) or a hydrogen (H) at the 5-position (DX 1) (depicted as "up" in the absolute stereochemical formula depicted in that patent) and since one of the two hydrogens at that position had to be "up" in Pfizer's 6-deoxytetracyclines having two hydrogens at the 5-position, Pfizer knew that it could not distinguish those compounds from the absolute stereochemical formula depicted in the Belgian Patent. Thus Pfizer stated in the original specification of the Doxycycline application that Pfizer's 6-deoxytetracyclines having two hydrogen groups at the 5-position were "products of the present invention" (DX 5, p. 11), but did not claim them in the original claims (DX 5, pp. 52-54; DX 2; Pfizer Brief dated September 9, 1974; Pfizer Brief dated March 7, 1975, p. 25).

21. At the time the Doxycycline application was filed, Pfizer believed, based on its prosecution of the parent Doxycycline application (DX 21), that the Patent Office might insist on the presentation of product-by-process claims if it revealed its uncertainties about absolute stereochemistry (DX 21, pp. 13, 38 and 47). Pfizer still believed that the Patent Office might insist on the presentation of product-by-process claims if it revealed its uncertainties about absolute stereochemistry on April 25, 1962, and still so believed on December 18, 1962. (DX 6; DX 8; Tr. January 31, 1975, pp. 420-421).

22. The last draft of the Doxycycline application dated May 2, 1961 stated, at Pfizer's patent agent Charles Knuth's (Knuth) suggestion, that

> These new tetracyclines possess a definite microbiological activity against a variety of Gram-positive and Gram-negative microorganisms and are appropriately designated as 6-epi-6-deoxytetracyclines since the steric configuration of the 6-methyl group is opposite to that of the known 6-deoxytetracyclines. Thus, the nomenclature '6-epi' as employed herein, is completely analogous to the accepted nomenclature for naming the known 4-epitetracyclines. *However, it should be understood that inasmuch as the stereochemical relationship between the 6-methyl group of the known 6-deoxytetracyclines and the parent (6-oxygenated) tetracyclines has not yet been established, the same is true with respect to the relationship between the new substances and the parent tetracyclines.* (Emphasis added; DX 23; DX 24).

Pfizer deleted this italicized sentence from the last draft prior to filing the Doxycycline application.

23. In the original specification of the Doxycycline application Pfizer deliberately did not state whether Doxycycline had the same or the opposite stereochemical configuration at the 6-position from its naturally produced parent fermentation product, oxytetracycline, and did not state whether or not the "known 6-deoxytetracyclines" (*e.g.*, the McCormick 6-deoxy compound) had the same or the opposite stereochemical configuration at the 6-position from their naturally produced parent fermentation products, *i.e.*, oxytetracycline (DX 2).

24. In the original specification of the Doxycycline application Pfizer did not disclose any absolute stereochemistry, did not disclose its belief as to the absolute stereochemistry of the McCormick 6-deoxy compound and doxycycline at the 6-position or its uncertain belief as to the absolute stereochemistry of the McCormick 6-deoxy compound and Doxycycline at the 5-position, and did not disclose that it had not proven its said beliefs. (DX 5; Pfizer Brief dated August 8, 1974).

25. On or about March 29, 1962 Pfizer brought the Belgian Patent to the attention of the Patent Office during an interview by Oglesby with Examiner Adams (the March 1962 interview) (Oglesby Affidavit dated March 18, 1975, paragraph 12, p. 3). During the interview Oglesby informed Examiner Adams that Pfizer believed that the absolute stereochemical formula depicted in the Belgian Patent was incorrect at the 5-position and that Pfizer further believed that the absolute stereochemical formula depicted in the Belgian Patent did not correctly depict the McCormick 6-deoxy compound at the 6-position (Oglesby Affidavit dated March 18, 1975, paragraphs 12, 13 and 14, p. 3). Oglesby did not reveal to Examiner Adams during that interview either Pfizer's belief that the stereochemical formula in the Belgian Patent depicted Doxycycline at the 6-position or Pfizer's uncertain belief that Doxycycline could be distinguished at the 5-position from the absolute stereochemical formula depicted in the Belgian Patent (DX 7).

26. In its first amendment to the Doxycycline application on April 26, 1962, Pfizer did not disclose its

belief that the absolute stereochemical formula depicted in the Belgian Patent depicted Doxycycline at the 6-position or its uncertain belief that Doxycycline could be distinguished from the absolute stereochemical formula depicted in the Belgian Patent at the 5-position. In this amendment Oglesby referred to the fact of the March 1962 interview but did not state that he had informed Examiner Adams of the Belgian Patent and did not state that Pfizer believed that the stereochemical formula depicted in the Belgian Patent depicted Doxycycline at the 6-position or that Pfizer had an uncertain belief that the Belgian Patent did not depict Doxycycline at the 5-position (DX 5, pp. 65-67). This amendment concluded with a request for reconsideration and allowance of the claims (DX 5, p. 67).

27. On April 26, 1962 Oglesby wrote a memorandum to his files expressing concern that disclosure to the Patent Office of uncertainties regarding absolute stereochemistry might limit Pfizer to product-by-process claims (DX 6, p. 2).

28. On October 30, 1962 the Patent Office in the second Office Action, by Examiner Berg, cited, *inter alia*, the Belgian Patent and rejected the compound (product) claims for Doxycycline and other compounds as anticipated under 35 U.S.C. §102 (DX 5, p. 68).

29. On December 17, 1962 Knuth informed Oglesby of Pfizer's continued and increased uncertainty as to the absolute stereochemistry of Doxycycline at the 5-position, citing a publication; Muxfeldt, Angew.

Chem. Internat. Edit., pp. 372-381 (1962), (Muxfeldt publication) giving two possible alternative absolute stereochemical configurations for the natural parent fermentation produced oxytetracycline, one in which the hydroxyl group at the 5-position was "up" (as depicted in the Belgian Patent) and one in which it was "down" (DX 20).

30. In a memorandum to his files dated December 18, 1962 Oglesby noted Pfizer's continued and increased uncertainty as to the absolute stereochemical configuration of Doxycycline at the 5-position, and outlined his proposed further strategy not to reveal Pfizer's increased uncertainty about the absolute stereochemical configuration of Doxycycline at the 5-position to the Patent Office unless other arguments failed to overcome the Examiner's rejection based on the Belgian Patent (DX 8).

31. On or about March 6, 1963 Oglesby and Knuth interviewed Examiner Berg (March 1963 interview) and informed him that the Muxfeldt publication had created some uncertainty as to the absolute stereochemical configuration of Doxycycline at the 5-position (Oglesby Affidavit dated March 18, 1975, paragraph 15, p. 3; Knuth Memo to his files dated March 12, 1963, DX 20). Examiner Berg responded that because of that uncertainty Pfizer could no longer rely on its belief that the absolute stereochemical formula depicted in the Belgian Patent did not depict Doxycycline at the 5-position, and indicated that the product (compound) claims would be rejected (Tr. January 31, 1975).

32. Shortly after the March 1963 interview Oglesby learned of the decision in *In re Le Grice*, 301 F.2d

929, 133 U.S.P.Q. 365 (C.C.P.A. 1962) and, beginning about April 24, 1963, believed that *In re Le Grice* overruled the von Bramer Doctrine and mooted the possible use of the absolute stereochemical formula depicted in the Belgian Patent as an anticipation of Doxycycline (Oglesby Affidavit dated March 18, 1975, paragraph 17, p. 4).

33. On April 30, 1963 Pfizer filed a second amendment in the Doxycycline application (DX 5, pp. 69-74). In the remarks accompanying this amendment, Oglesby referred to the fact of the March 1963 interview but he did not state that he had informed Examiner Berg of Pfizer's uncertainty as to the absolute stereochemical configuration of Doxycycline at the 5-position, or that Examiner Berg had stated that those uncertainties precluded Pfizer from relying on its belief that the absolute stereochemical formula depicted in the Belgian Patent at the 5-position did not depict Doxycycline and indicated that the product (compound) claims would be rejected.

34. The April 30, 1963 amendment stated that the Belgian Patent "accidentally" depicted the absolute stereochemical configuration of Pfizer's 6-deoxytetracyclines at the 6-position, and cited the Muxfeldt publication and two other prior art publications (DX 5, pp. 70-71). Oglesby then argued that since the Belgian Patent did not enable those skilled in the art to make the compounds depicted in the stereochemical formula under the *Le Grice* decision the Belgian Patent could not be relied on as an anticipation. Based on this argument Pfizer also added claims in the amendment directed to its 6-deoxytetracyclines which did not have an hydroxyl (OH) group at the

5-position (and which had two hydrogen atoms (H) at the 5-position) and which Pfizer had not previously claimed because it believed they were anticipated by the Belgian Patent under the von Bramer Doctrine (see Finding 20, *supra*). Pfizer did not state or indicate in that amendment that Pfizer was uncertain as to the absolute stereochemical configuration of Doxycycline at the 5-position, either because of the disclosures of the three cited publications or for any other reason.

The disclosures of the Muxfeldt publication are set forth in Finding 29, *supra*. Of the two remaining publications, one relates only to oxytetracycline, as did Muxfeldt, and the other, by Pfizer's von Wittenau et al. (DX 28), does not disclose any uncertainty at the 5-position.

Pfizer did not state or indicate in the April 30, 1963 amendment, or disclose to the Patent Office at any other time during the prosecution of the Doxycycline application, that it knew that Doxycycline, the McCormick 6-deoxy compound and the natural fermentation produced oxytetracycline compound all had the same relative stereochemical configuration.

35. In December 1963 Pfizer scientist von Wittenau theorized that in Doxycycline the hydroxyl group (OH) at the 5-position was "up" (as shown in the Belgian Patent) and prepared a technical paper summarizing the basis for his theory and submitted it to Pfizer's Patent Department for pre-publication approval (von Wittenau Affidavit dated March 27, 1975, paragraph 20, p. 4; DX 9). Von Wittenau's theory

created additional uncertainty at Pfizer as to the absolute stereochemical configuration of Doxycycline at the 5-position, and Pfizer deferred publication of the proposed von Wittenau paper pending review of von Wittenau's theory with its consultant Dr. Woodward (DX 12).

36. On or about April 14, 1964 Oglesby contacted the Patent Office by telephone (the April 1964 interview) and advised Examiner Modance of the prospective meeting with Woodward which was expected to "shed more conclusive light on the structure of the compounds under discussion" (DX 12, p. 4; Oglesby Affidavit dated March 18, 1975, p. 4, paragraph 19). During the April 1964 interview Oglesby was advised by Examiner Modance that the chemical section in the Patent Office (which section was acting on the Doxycycline application) still followed the von Bramer Doctrine notwithstanding the *Le Grice* decision (DX 12, p. 5).

37. As of April 14, 1964, because of Pfizer's increased uncertainty as to the absolute stereochemical configuration of Doxycycline at the 5-position and the continued application of the von Bramer Doctrine by the chemical section of the Patent Office, Pfizer was still in doubt as to whether the Belgian Patent would be applied by the Patent Office as an anticipation of Doxycycline under 35 U.S.C. §102. Pfizer did not inform the Patent Office of its increased uncertainty as to the absolute stereochemical configuration of Doxycycline at the 5-position.

38. By June of 1964, after the meeting with Dr. Woodward, Pfizer was still uncertain as to the absolute stereochemical configuration of Doxycycline at the 5-position which was, in the words of Pfizer patent agent Knuth, "completely up in the air again" (DX 13).

39. In June of 1964 Oglesby was still uncertain whether Examiner Modance would accept his *Le Grice* argument, notwithstanding a decision, *In re Brown*, 329 F.2d 1006 (C.C.P.A. 1964), casting yet further doubt on the von Bramer Doctrine (DX 14, p. 2). Oglesby concluded at that time that he would disclose Pfizer's continued uncertainty as to the abolute stereochemical configuration of Doxycycline at the 5-position to Examiner Modance only if the Examiner was willing to follow the *Le Grice* and *Brown* decisions and thus disregard the absolute stereochemical formula depicted in the Belgian Patent as an anticipation under 35 U.S.C. § 102 (DX 14, p. 2).

40. On or about July 9, 1964 Oglesby in an interview with Examiner Modance (July 1964 interview) advised him that Pfizer was uncertain as to the absolute stereochemical configuration of Doxycycline at the 5-position (DX 15; Oglesby Affidavit dated March 18, 1975, paragraph 20).

41. In the third amendment filed on July 23, 1964 Pfizer made the fact of the July 1964 interview formally of record (DX 5, pp. 89-90) but did not state in the amendment that Pfizer was uncertain as to the absolute stereochemical configuration of Doxycycline at the 5-position or that Pfizer's uncertainties as to the absolute stereochemical configuration of Doxycycline at the 5-position had been disclosed to or discussed with Examiner Modance.

42. During the prosecution of the Doxycycline application Examiner Adams was not interested in the absolute stereochemical configuration of either the McCormick 6-deoxy compound or Pfizer's 6-deoxytetracyclines because Examiner Adams did not know of Pfizer's belief that the Belgian Patent depicted the absolute stereochemical formula of Doxycycline at the 6-position or Pfizer's uncertainties as to whether the Belgian Patent depicted the absolute stereochemical formula of Doxycycline at the 5-position (Adams Affidavit dated October 9, 1974, paragraph 7, p. 4; Adams Affidavit dated February 3, 1975, paragraph 4, p. 2).

43. Had Examiner Adams known at any time between the date of filing of the Doxycycline application and April 29, 1962 (the date that Examiner Adams left the Patent Office) that Pfizer was uncertain as to whether or not the Belgian Patent correctly depicted the absolute stereochemical configuration of Doxycycline at the 5-position, Examiner Adams would have rejected and product (compound) claims of the Doxycycline application as anticipated by the Belgian Patent under 35 U.S.C. §102 (Adams Affidavit dated February 3, 1975, paragraph 4, p. 2). Had Pfizer after such rejection not been able to establish by scientific proof, *i.e.*, scientific evidence which quantitatively and qualitatively would be regarded as convincing by a prudent, experienced chemist skilled in the art, that the absolute stereochemical formula in the Belgian Patent did not depict Doxycycline, Examiner Adams would at any time prior to April 29, 1962 (the date that Examiner Adams left the Patent Office) have issued a final rejection, again based on 35 U.S.C. §102 (Adams

Affidavit dated February 3, 1975, paragraph 4, p. 2; PX 9, paragraph 7, p. 7).

44. Pfizer did not know and did not prove at any time prior to on or about November 13, 1964 whether or not its uncertain belief that the Belgian Patent did not depict the absolute stereochemical configuration of Doxycycline at the 5-position was correct or incorrect (DX 12, 13 and 14).

45. On or about November 13, 1964 Pfizer first believed that in Doxycycline the absolute stereochemical configuration of the hydroxyl group (OH) at the 5-position was "down" (DX 4; Pfizer's Supplemental Response dated February 11, 1974 to Defendant USV's Interrogatory dated July 13, 1973).

46. Pfizer did not at any time during the prosecution of the Doxycycline application disclose to the Patent Office when it believed for the first time that in Doxycycline the absolute stereochemical configuration of the hydroxyl group (OH) at the 5-position was "down".

47. With the exception of the March 1963, April 1964 and July 1964 interviews Pfizer did not at any time during the prosecution of the Doxycycline application disclose to the Patent Office that from the time of the filing of the Doxycycline application and until on or about November 13, 1964 it had either uncertainties or increased uncertainties, which it had not proven correct or incorrect, as to whether or not the Belgian Patent depicted the absolute stereochemical configuration of Doxycycline at the 5-position.

D. Conclusions of Law Concerning Pfizer's Failure to Disclose the Belgian Patent and its Beliefs and Uncertainties Concerning the Stereochemistry of Doxycycline to the Patent Office

1. When Pfizer filed the Doxycycline application it deliberately withheld informing the Patent Office of the Belgian Patent.

2. When Pfizer filed the Doxycycline application it deliberately withheld from the Patent Office its belief that the Belgian Patent depicted Doxycycline at the 6-position and its uncertainty that the Belgian Patent did not depict Doxycycline at the 5-position.

3. When Pfizer filed the Doxycycline application it knew that the Belgian Patent was equally pertinent if not more pertinent to the patentability of Doxycycline than the McCormick 6-deoxy compound, and was therefore equally pertinent prior art, if not the most pertinent prior art.

4. When Pfizer filed the Doxycycline application it had a duty to bring the Belgian Patent to the attention of the Patent Office with reasonable diligence.

5. When Pfizer filed the Doxycycline application it had a duty to disclose to the Patent Office its belief that the Belgian Patent depicted Doxycycline at the 6-position and its uncertain belief that the Belgian Patent did not depict Doxycycline at the 5-position with reasonable diligence.

6. When Pfizer filed the Doxycycline application the significance of the absolute stereochemical formula depicted in the Belgian Patent as an anticipation under 35 U.S.C. §102 or in limiting the product (compound) claims to product-by-process claims under 35 U.S.C.

§112, depended upon the disclosure of that depiction and Pfizer's knowledge, belief or uncertain belief concerning the absolute stereochemical configuration of Doxycycline at the 5- and 6-positions. The Patent Office could not determine the significance of the absolute stereochemical formula depicted in the Belgian Patent unless Pfizer disclosed its belief that the Belgian Patent depicted Doxycycline at the 6-position and its uncertain belief that the Belgian Patent did not depict Doxycycline at the 5-position. (Tr. January 24, 1975, pp. 123-124).

7. When Pfizer filed the Doxycycline application it deliberately disclosed only the relative stereochemistry of Doxycycline at the 6-position and the relative stereochemistry of the McCormick 6-deoxy compound at the 6-position in order to withhold from the Patent Office the significance of the Belgian Patent as an anticipation under 35 U.S.C. §102 or in limiting the product (compound) claims to product-by-process claims under 35 U.S.C. §112 based on its belief and uncertain belief concerning the absolute stereochemistry of Doxycycline at the 6- and 5-positions, respectively.

8. At the time Pfizer filed the Doxycycline application the Belgian Patent, coupled with Pfizer's belief and uncertain belief concerning the absolute stereochemistry of Doxycycline at the 6- and 5-positions, respectively, was material to the issue of whether or not Doxycycline was anticipated under 35 U.S.C. §102, and was material to the issue of whether or not only product-by-process claims were allowable under 35 U.S.C. §112.

9. Pfizer is estopped to assert that it brought the Belgian Patent to the Examiner's attention in the March 1962 interview because it failed to state in

writing and of record that it brought the Belgian Patent to the attention of the Patent Office in that interview. Alternatively, if Pfizer is not estopped, then Pfizer deliberately failed to bring the Belgian Patent to the attention of the Patent Office until the March 1962 interview.

10. Pfizer is estopped to assert that it disclosed its uncertainties concerning the absolute stereochemistry of Doxycycline at the 5-position to the Patent Office in the March 1963, April 1964 and July 1964 interviews because it failed to state in writing and of record that it made these disclosures to the Patent Office during those interviews. Alternatively, if Pfizer is not estopped, then Pfizer deliberately failed to disclose its uncertainties concerning the absolute stereochemistry of Doxycycline at the 5-position to the Patent Office until the March 1963 interview.

11. Pfizer is estopped to assert that it disclosed its beliefs concerning the absolute stereochemistry of Doxycycline at the 6-position to the Patent Office in the March 1963 interview because it failed to state in writing and of record that it made that disclosure to the Patent Office in that interview. Alternatively, if Pfizer is not estopped then Pfizer deliberately failed to disclose its belief concerning the absolute stereochemistry of Doxycycline to the Patent Office until the March 1963 interview.

12. The Belgian Patent and Pfizer's belief and uncertainties respecting the absolute stereochemistry of Doxycycline at the 6-position and 5-position, respectively (and, therefore, the relationship between Doxycycline and the absolute stereochemical formula depicted in the Belgian Patent) were material to the issues of whether or not Doxycycline was anticipated under

35 U.S.C. §102 or whether or not only product-by-process claims were allowable under 35 U.S.C. §112 for a period of more than three years after the Doxycycline application was filed and until on or after June, 1964 when the Patent Office Examiners in charge of the Doxycycline application accepted Pfizer's argument that the *Le Grice* and *Brown* decisions overruled the von Bramer Doctrine.

13. Regardless of the immateriality of the absolute stereochemistry depicted in the Belgian Patent and Pfizer's beliefs and uncertainties concerning the absolute stereochemistry of Doxycycline at the 6- and 5-positions on or after June, 1964, and based on the estoppels set forth in Conclusions 9, 10 and 11, *supra,* Pfizer's deliberate failure to bring the Belgian Patent to the attention of the Patent Office before the October 30, 1962 Official Action (citing the Belgian Patent) and its deliberate delay in disclosing its belief concerning the absolute stereochemistry of Doxycycline at the 6-position to the Patent Office until the April 30, 1965 amendment, and its intentional failure to disclose its uncertain belief concerning the absolute stereochemistry of Doxycycline at the 5-position to the attention of the Patent Office during the prosecution of the Doxycycline application, constitutes a breach of its duty to bring pertinent prior art and its belief and uncertain belief concerning the applicability of that prior art as an anticipation to the attention of the Patent Office with reasonable diligence. It also constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all pertinent prior art, facts and beliefs which may be relevant to an issue of patentability.

Alternatively, if there is no estoppel Pfizer's deliberate delay in bringing the Belgian Patent to the attention of the Examiner until March 1962 and its deliberate delay in disclosing its belief concerning the absolute stereochemistry of Doxycycline at the 6-position until March, 1963, and its deliberate delay in disclosing its uncertainties concerning the absolute stereochemistry of Doxycycline at the 5-position until March 1963, constitutes a breach of its duty to bring pertinent prior art and its belief and uncertain belief concerning the applicability of that prior art as an anticipation to the attention of the Patent Office with reasonable diligence, and also constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all pertinent prior art, facts and beliefs which may be relevant to an issue of patentability.

E. The Facts Respecting Pfizer's False Analogy Between Doxycycline and the Prior Art "Epimers" of the Natural Fermentation Produced Tetracyclines

1. Prior to the grant of the Doxycycline patent Examiner Adams knew from the prior art that there were tetracycline epimers which were the opposite of the natural fermentation produced tetracyclines and which had lower antibacterial activities than the natural fermentation produced tetracyclines (Adams Affidavit dated February 3, 1975, p. 7, paragraph 12).

2. Prior to the grant of the Doxycycline patent Examiner Adams did not know of any tetracycline epimers which were the opposite of the natural fermentation produced tetracyclines and which had antibacterial

activities superior to the natural fermentation produced tetracyclines (Adams Affidavit dated February 3, 1975, paragraph 12, p. 7).

3. Prior to the issuance of the Doxycycline patent there was no epimer which was the opposite of a natural fermentation produced tetracycline which had antibacterial activities superior to the natural fermentation produced tetracyclines.

4. At all times during the prosecution of the Doxycycline application Pfizer believed that Doxycycline had the same stereochemical configuration at the 6-position as its parent natural fermentation produced tetracycline (both "down"), *i.e.*, oxytetracycline (DX 30, 31 and 40).

5. The Doxycycline application describes the claimed compounds as "6-epi-6-deoxytetracyclines", and states that "the nomenclature '6-epi' as employed herein, is completely analogous to the accepted nomenclature for naming the known 4-epitetracyclines" (DX 5, p. 1).

6. The known 4-epi tetracyclines were epimers which were the opposite of natural fermentation produced tetracyclines and were so recognized by those skilled in the art.

7. In a publication dated October 20, 1958 (80 JACS 5572) Cyanamid's McCormick et al. disclosed and depicted 5a-epi-tetracyclines. The 5a-epi-tetracyclines were epimers which were the opposite of the natural fermentation produced tetracyclines.

8. In the first rejection of the Doxycycline application on October 26, 1961, Examiner Adams cited the prior art references which described the 4- and 5a-epi-tetracyclines which he believed were (and in

fact were) the opposite of natural fermentation produced tetracyclines at other asymmetric centers of the nucleus and rejected Pfizer's product (compound) claims to Doxycycline and other compounds as obvious under 35 U.S.C. §103, stating that since "epimers" were well known at other positions in the tetracycline nucleus, Pfizer's "epimers" were only a routine development (DX 5, pp. 58-59; Tr. April 17, 1975, p. 200).

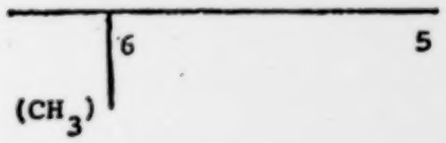
9. In the first amendment filed April 26, 1962 Pfizer stated that Doxycycline was not a routine or obvious development, because the antibacterial activity of Doxycycline was superior to the antibacterial activity of the McCormick 6-deoxy compound "of normal as opposed to epimeric configuration", and further stated that such superiority was unexpected. To support the statement that the superiority of Doxycycline was unexpected, Pfizer compared Doxycycline (which it believed to have the same configuration at the 6-position as the natural fermentation produced tetracyclines, i.e., "down") with prior art "epimers" at other asymmetric centers on the nucleus (all of which it knew were the opposite of the natural fermentation produced tetracyclines, i.e., "up") and stated that while the prior art "epimers" had less antibacterial activity than their "conventional" counterparts, Doxycycline had more antibacterial activity than the prior McCormick 6-deoxy compound (DX 5, p. 66).

10. In his final rejection of the Doxycycline application on January 19, 1965, based in part on obviousness under 35 U.S.C. §103, Examiner Adams erroneously concluded that Doxycycline had an absolute stereochemical configuration at the 6-position which was the opposite of the natural fermentation produced tetracyclines; stating that ". . . the claimed compounds

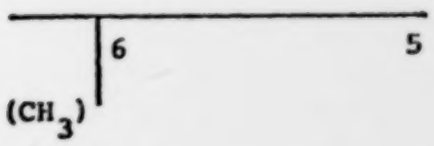
have a methyl group in the 6-position which allegedly is oriented in a different manner than the corresponding compounds produced by fermentation methods," and further stated that it was "well known . . . that epimerization at various positions reduced the antibiotic properties of the compound. . . ." (DX 5, pp. 93-94).

11. In that rejection Examiner Adams erroneously stated that the stereochemical configuration of oxytetracycline, the McCormick 6-deoxy compound and Doxycycline at the 6-position were as follows:

Oxytetracycline



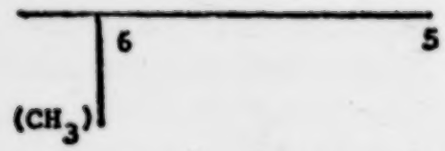
McCormick
6-Deoxy Compound



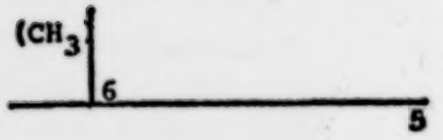
Doxycycline

On January 19, 1965 Pfizer believed that the absolute stereochemical configuration of oxytetracycline, the McCormick 6-deoxy compound and Doxycycline at the 6-position were as follows:

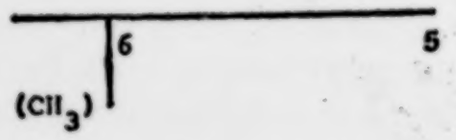
Oxytetracycline



McCormick
6-Deoxy Compound



Doxycycline



12. In its fifth amendment dated March 5, 1965 responding to the January 19, 1965 final rejection, Pfizer stated that "the claimed compounds have a methyl group in the 6-position which is oriented in the opposite direction to that of the known 6-deoxytetracyclines [e.g., the McCormick 6-deoxy compound] produced by hydrogenation of fermentation produced tetracyclines . . ." and that "the prior art catalytic hydrogenation of fermentation produced tetracyclines not only replaces the 6-OH substituent with a hydrogen substituent but also reverses the spatial orientation of the 6-methyl substituent, the orientation of the hydrogen substituent being opposite thereto in the final product. . . ." (DX 5, pp. 100-101).

13. The language quoted in Finding E-12, *supra*, told the Patent Office that at the 6-position the relative configuration of Doxycycline was the opposite of the McCormick 6-deoxy compound which was the opposite of the natural fermentation produced tetracyclines. That

language, while technically correct, does not state that Doxycycline and the natural fermentation produced tetracyclines have the same configuration at the 6-position, although it can be inferred that if the methyl group (CH_3) at the 6-position has one epimer which is "up" and one epimer which is "down", and if the relative configuration of Doxycycline is the opposite of the McCormick 6-deoxy compound; and the relative configuration of the McCormick 6-deoxy compound is the opposite of the natural fermentation produced tetracyclines; then in Doxycycline the methyl group at the 6-position must be "down" and the same as the natural fermentation produced tetracyclines.

14. In a draft of the March 5, 1965 amendment Pfizer stated that

> *this rejection states the claimed compounds have a methyl group in the 6-position which allegedly is oriented in a different manner than the corresponding compounds produced by fermentation methods. Actually . . . the claimed compounds have a methyl group in the 6-position which is oriented in precisely the same manner as the corresponding 6-OH containing compounds produced by fermentation methods . . . . (DX 37).*

The above italicized statement was deleted from the March 5, 1965 amendment before filing.

15. On February 11, 1965 Knuth wrote to Oglesby and stated that in Doxycycline ". . . the 6-methyl group has the same configuration as that of the parent fermentation produced antibiotic" (DX 26).

16. In further response to the January 19, 1965 final rejection, Pfizer's March 5, 1965 amendment repeated the representations set forth in its April 26,

1962 amendment that the superior antibacterial activities of Doxycycline were unexpected because of the low antibacterial activities of prior tetracycline "epimers" (DX 5, p. 104), but did not relate this statement to the language quoted in Finding E-12, *supra*.

17. At all times during the prosecution of the Doxycycline application including the date of allowance and the date of issuance, Examiner Adams believed that Doxycycline and the other claimed compounds had a stereochemical configuration at the 6-position opposite that of their parent natural fermentation produced tetracyclines, *e.g.*, oxytetracycline, and that the superior antibacterial activity of Doxycycline was, because of this difference, unexpected (Adams Affidavit dated February 3, 1975, paragraph 12, p. 7 and paragraph 13, p. 8); but that the unexpected superiority of Doxycycline was immaterial to patentability (Adams Affidavit dated February 24, 1975, paragraph 13, pp. 17-18).

F. Conclusions of Law Concerning Pfizer's False Analogy Between Doxycycline and the Prior Art "Epimers".

1. At page 1 of the specification, and in the April 25, 1962 and the March 5, 1965 amendments, Pfizer deliberately misrepresented, by falsely analogizing Doxycycline to prior art tetracycline "epimers" at other asymmetric positions on the tetracycline nucleus, that Doxycycline had unexpected superior antibacterial activities.

2. Pfizer deliberately failed to state in clear, concise and readily understood language and further, deliberately used confusing and unclear language in the March 5, 1965 amendment to conceal, that the absolute

stereochemical configuration of Doxycycline was the same as the parent natural fermentation produced tetracyclines at the 6-position. This language was in turn designed to conceal Pfizer's false analogy that Doxycycline was comparable to the prior art tetracycline epimers and therefore unexpectedly superior.

3. Pfizer's deliberate misrepresentations in the specification and in the April 25, 1962 and March 5, 1965 amendments falsely analogizing Doxycycline to the prior art tetracycline "epimers", misled the Patent Office to erroneously conclude from the date of the January 19, 1965 Office Action to the date of the issuance of the Doxycycline patent that the stereochemistry of Doxycycline was opposite to that of the natural fermentation produced tetracyclines at the 6-position.

4. Pfizer's deliberate misrepresentations in the specification and in the April 25, 1962 and March 5, 1965 amendments falsely analogizing Doxycycline to prior art tetracycline "epimers" was not material to the issue of whether or not Doxycycline was patentable under 35 U.S.C. §103.

5. Pfizer deliberately falsely analogized Doxycycline to the prior art tetracycline "epimers" in the specification and in the April 25, 1962 and March 5, 1965 amendments, and its deliberate use of misleading and unclear language in the March 5, 1965 amendment. All of which was designed to conceal the fact that Doxycycline had the same absolute stereochemical configuration as its parent natural fermentation produced tetracycline at the 6-position, and which was in turn designed to conceal Pfizer's false analogy that Doxycycline was comparable to the prior art tetracycline epimers at the 6-position, constitutes inequitable conduct

which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure of all facts which may be relevant to an issue of patentability.

G. The Facts Respecting Pfizer's Misrepresentations to the Patent Office Concerning the Antibacterial Activity of Doxycycline

1. As filed, the specification of the Doxycycline application states that Doxycycline and the other claimed 6-deoxytetracycline compounds "have particularly good *in vivo* effectiveness" [in animal tests], and that these compounds "are useful by virtue of their high order of activity against a variety of microorganisms, both *in vivo* and *in vitro*" [in test tubes] (DX 5, p. 11).

2. As filed, the specification also compares the *in vitro* activities of Doxycycline and the McCormick 6-deoxy compound against a number of organisms stating that Doxycycline is markedly superior to the McCormick 6-deoxy compound when tested against an antibiotic resistant strain Micrococcus pyogenes var. aureus 400 ("Staph 400"), and is equivalent to the McCormick 6-deoxy compound when tested against an antibiotic susceptible strain Micrococcus pyogenes var. aureus 5 ("Staph 5") (DX 5, p. 12).

3. On February 14, 1961 Pfizer's Dr. McBride reported the "side by side comparison of Doxycycline with tetracycline in mice infected with [Staph 5] and [Staph 400]" and concluded that Doxycycline "remains inactive against [Staph 400]" (DX 43).

4. At the time the Doxycycline application was filed, Pfizer knew that Doxycycline was active against

Staph 400 *in vitro* but inactive against Staph 400 *in vivo* (DX 42 and 43).

5. In its rejection dated October 26, 1961 the Patent Office by Examiner Adams rejected the product claims of the Doxycycline application as obvious under 35 U.S.C. §103 (DX 5, p. 59).

6. In its first amendment dated April 26, 1962 responding to the October 26, 1961 rejection Pfizer stated that Doxycycline had outstanding antibacterial activities both *in vitro* and *in vivo* (DX 5, p. 66) and included two affidavits—one by Pfizer's Dr. English and one by Pfizer's Dr. McBride—in support thereof (DX 5, pp. 60-64).

7. The English Affidavit (DX 5, pp. 61-62) set forth the same *in vitro* data incorporated in the original application with respect to the activity of Doxycycline against Staph 5 and Staph 400. The McBride Affidavit (DX 5, pp. 63-64) stated that Doxycycline was effective *in vivo* against Staph 5 when administered orally and by injection.

8. Pfizer did not, in its April 26, 1962 amendment, or at any other time during the prosecution of the Doxycycline application disclose to the Patent Office its knowledge that Doxycycline was inactive *in vivo* against Staph 400.

9. In the McBride Affidavit Pfizer indicated that Doxycycline was about 36 times as effective as the McCormick 6-deoxy compound against Staph 5 *in vivo* when administered orally and possessed high activity against Staph 5 when administered by injection (DX 5, pp. 63-64).

10. In the second Office Action on October 30, 1962 the Patent Office, by Examiner Berg, stated

that "applicants have submitted two affidavits under Rule 132 which have been carefully considered and are deemed persuasive in overcoming the rejection . . . and are deemed sufficient to overcome the rejection. . . ."

11. On June 20, 1964 Pfizer scientists English and Blackwood, among others, knew that further *in vivo* tests of Doxycycline against Staph 5 showed that it was less than one-half as effective as reported in the McBride affidavit when administered orally, and only about one-fifth as effective as reported in the McBride affidavit when administered by injection (DX 44; English Affidavit dated March 27, 1975, paragraph 2).

12. On January 19, 1965, the Patent Office by Examiner Adams entered a final rejection of the Doxycycline application on the ground that Doxycycline was obvious under 35 U.S.C. §103 (DX 5, pp. 94-95).

13. In its fifth amendment dated March 5, 1965, in response to the final rejection of January 18, 1965, Pfizer stated that Doxycycline was about 36 times as effective as the McCormick 6-deoxy compound against Staph 5 when administered orally, and that such difference was evidence that Doxycycline was not obvious (DX 5, p. 104).

14. Pfizer did not, in its March 5, 1965 amendment or at any other time prior to the grant of the Doxycycline patent in August 1965, disclose to the Patent Office its June 20, 1964 knowledge that its most recent *in vivo* tests of Doxycycline against Staph 5 showed that Doxycycline was less than one-half as effective as reported in the McBride Affidavit when administered orally, and only one-fifth as effective as

reported in the McBride Affidavit when administered by injection.

15. During the prosecution of the Doxycycline application Examiner Adams would have been interested in; and considered material, any evidence in Pfizer's possession inconsistent with the data presented in the English and McBride Affidavits, including evidence of inconsistencies between the actual *in vivo* antibacterial activities of Doxycycline and the *in vitro* activities of Doxycycline (Adams Affidavit dated February 3, 1975, pp. 5-6), even though he knew during the prosecution of the Doxycycline application that an antibiotic displaying *in vitro* activity against a particular organism is not necessarily active *in vivo* against the same organism (PX 9, paragraph 10, pp. 11-12).

H. Conclusions of Law Concerning Pfizer's Misrepresentations to the Patent Office Regarding the Antibacterial Activity of Doxycycline

1. Pfizer deliberately disclosed only the favorable *in vitro* and *in vivo* activity data and deliberately withheld the unfavorable *in vivo* activity data from the Patent Office at all times during the prosecution of the Doxycycline application. Pfizer did this by deliberately concealing the fact that Doxycycline was inactive against Staph 400 *in vivo,* and by deliberately withholding from the Patent Office from June 20, 1964 and thereafter throughout the prosecution of the Doxycycline application, its June 20, 1964 knowledge that Doxycycline was less effective against Staph 5 *in vivo* than it had reported in the April 25, 1962 amendment and by representing in the March 5, 1965 amendment that Staph 5 was as effective *in vivo* as it had earlier reported.

2. Pfizer's deliberate concealment of the fact that Doxycycline was inactive against Staph 400 *in vivo* and Pfizer's deliberate withholding of, and misrepresentation of its June 20, 1964 knowledge that Doxycycline was less effective *in vivo* against Staph 5 than it had earlier reported was material to the issue of whether or not Doxycycline was obvious under 35 U.S.C. §103.

3. Pfizer's deliberate concealment of the fact that Doxycycline was inactive against Staph 400 *in vivo,* and its deliberate withholding of and misrepresentation of its June 20, 1964 knowledge that Doxycycline was less effective against Staph 5 *in vivo* than it had earlier reported, constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure of all facts which may be relevant to an issue of patentability.

I. The Facts Respecting Pfizer's Misrepresentations to the Patent Office Concerning the Prior Inherent Coproduction of Doxycycline

1. In the late 1950's, prior to the filing of the Doxycycline application, scientists at both Pfizer and Cyanamid had hydrogenated oxytetracycline and produced the McCormick 6-deoxy compound. This work was disclosed in Pfizer's Stephens et al. paper in the Journal of the American Chemical Society, Vol. 80, pp. 5324-25 (1958) (JACS reference) and U.S. Patent No. 3,019,260 and Belgian Patent No. 565,025 (cited references), and in the Belgian Patent, all of which were cited during the prosecution of the Doxycycline application. None of the cited references state or indicate that in following the processes stated, Doxycycline is inherently coproduced.

2. Prior to filing the Doxycycline application, Pfizer knew that the hydrogenation of oxytetracycline to produce the McCormick 6-deoxy compound had been described in the prior art including the cited references and the Belgian Patent (DX 1; DX 2; Tr. March 17, 1975, p. 23).

3. In 1958 and 1959 (DX 47, 48), Pfizer filed two patent applications in the names of Stephens and Conover (Stephens applications), disclosing the production of the 6-deoxytetracyclines, including the McCormick 6-deoxy compound, by the hydrogenation of the corresponding tetracyclines, *e.g.*, oxytetracycline. In the Stephens applications Pfizer disclosed that in prior experimental work involving the hydrogenation of oxytetracycline (Stephens' prior work) they had produced a "trace" of an "additional active entity", which Stephens believed was Doxycycline, and stated that the "additional active entity" "may be the C-6 epimer of 6-deoxy-5-oxytetracycline . . ." (doxycycline)(DX 47, pp. 8, 11), and ". . . is thought to be the C-6 epimer of 6-deoxy-5-oxytetracycline . . ." (doxycycline) (DX 48, pp. 10, 14).

4. Prior to the filing of the Doxycycline application, Pfizer contemplated relying on the disclosures in the Stephens applications and filing a continuation-in-part application claiming Doxycycline as the invention of Stephens and Conover (DX 2). However, on Oglesby's advice Pfizer filed the Doxycycline application in the names of Messrs. Blackwood, Beereboom, Rennhard and Stephens (DX 20; DX 5, pp. 55-56).

5. When Stephens executed the oath for the Doxycycline application with Blackwood, Beereboom and Rennhard as one group of inventors he swore that he

did not know and did not believe that Doxycycline was ever known or used by any other group of inventors, *e.g.*, Stephens and Conover, prior to the Blackwood, Beereboom, Rennhard and Stephens invention (DX 5, pp. 55-56).

6. At the time of the filing of the Doxycycline application and continuously until June, 1964 Stephens believed that Doxycycline was inherently coproduced in Stephens' prior work and in following the process of one example of the Stephens applications (Stephens belief). Stephens further believed that if Doxycycline was inherently coproduced in accordance with the process described in the Stephens' applications it was also inherently coproduced in following the processes of the cited references and the Belgian Patent (Stephens' further belief) (DX 21, pp. 3, 12, 49 and 74; and Stephens' Affidavit dated March 27, 1975, paragraph 18, p. 3).

7. When Pfizer filed the Doxycycline application it did not disclose to the Patent Office the evidence (the Stephens evidence) obtained in Stephens' prior work and described in an example of each of the Stephens' applications (DX 47, pp. 10-11; DX 48, pp. 13-14) which indicated that Doxycycline had in fact been inherently coproduced.

8. When Pfizer filed the Doxycycline application it did not advise the Patent Office of Stephens' belief or Stephens' further belief.

9. In the October 30, 1962 Official Action, the Patent Office by Examiner Berg rejected the pertinent product claims for Doxycycline and other claimed compounds as anticipated under 35 U.S.C. §102 by the

Belgian Patent and U.S. Patent No. 3,019,260 and Belgian Patent No. 565,025 (DX 5, p. 68).

10. In its second amendment dated April 30, 1963, in response to the October 30, 1962 rejection, Pfizer represented to the Patent Office that Doxycycline was not in fact inherently coproduced by the Belgian Patent or by U.S. Patent No. 3,019,260 or by Belgian Patent No. 565,025, and that these references produced only the previously known 6-deoxytetracycline compounds, *i.e.*, the McCormick 6-deoxy compounds (DX 5, p. 70).

11. In its April 30, 1963 amendment Pfizer did not disclose the Stephens' evidence or Stephens' belief or Stephens' further belief.

12. On March 20, 1964 Oglesby stated in a memorandum to his files that Stephens believed that the amount of Doxycycline inherently coproduced in Stephens' prior work and in following the process of the Stephens' applications was ". . . of the same order of magnitude as tetracycline is produced in Duggar 2209 aureomycin fermentations" (DX 10).

13. On March 20, 1964 Pfizer knew that, if there was a basis for Stephens' belief and Stephens' further belief then the denial of inherent coproduction in its April 30, 1963 amendment was false (DX 10).

14. On April 14, 1964 Pfizer knew that it was still Stephens' belief that Doxycycline was inherently coproduced in his prior work and in the process described in the Stephens' applications. Pfizer also knew that it was still Stephens' further belief that Doxycycline was inherently coproduced in following the processes of the cited references and the Belgian Patent (DX 12).

15. During the Spring of 1964, at Oglesby's suggestion, Pfizer's Dr. Murai repeated Stephens' prior work (the Murai 1964 investigation), on which Stephens' belief and further belief were based, and obtained chromatographic evidence tending to indicate that Stephens' "additional active entity" was Doxycycline and ultraviolet spectral evidence indicating that the "additional active entity" was not Doxycycline (DX 35 and DX 52). During the Spring of 1964, Pfizer's Beereboom believed that chromatographic data was "much more effective" than ultraviolet spectral data in identifying Doxycycline (Beereboom deposition, DX 54, p. 310).

16. In June 1964, at the conclusion of the Murai 1964 investigation, Stephens was satisfied that the inherent coproduction of Doxycycline in his prior work had not been demonstrated and concluded that no detectable Doxycycline was inherently coproduced therein. (Stephens' Affidavit dated March 18, 1975, paragraph 18, p. 3).

17. In June 1964, at the conclusion of the Murai 1964 investigation, Pfizer concluded that it could not state unequivocally that the "additional active entity" previously produced in Stephens' prior work was not Doxycycline, but could state that it believed that it was not (Oglesby Affidavit dated March 18, 1975, paragraph 65, p. 9).

18. On July 9, 1964 Oglesby interviewed Examiner Modance (the July 1964 interview), and disclosed that Stephens' prior work might possibly have inherently coproduced Doxycycline. He also identified the Stephens' applications, disclosed that part of the conclusion of the Murai 1964 investigation which showed by ultra-

violet data that there was no inherent coproduction, and offered to apprise the Examiner of any further information he might request. Examiner Modance stated that the Patent Office could not consider the question of inherent coproduction since it was not suggested by any prior art and declined Pfizer's offer to make the facts respecting inherent coproduction of record (Oglesby Affidavit dated March 18, 1975, paragraphs 57 and 72, p. 10).

19. In its third amendment dated July 23, 1964 Pfizer made the fact of the July 1964 interview of record, but did not mention in that amendment any of Oglesby's discussion with Examiner Modance on July 9, 1964 (DX 5, pp. 89-90).

20. On February 23, 1965 Oglesby interviewed Examiner Adams (the February 1965 interview) and disclosed that Stephens' prior work might possibly have inherently coproduced Doxycycline, identified the Stephens' applications, again disclosed that part of the results of the Murai 1964 investigation, which showed by ultraviolet data that there was no inherent coproduction, and offered to apprise him of any further information he might request. Examiner Adams, like Examiner Modance, stated that the Patent Office could not consider the question of inherent coproduction since it was not suggested by any prior art and declined Pfizer's offer to make the facts respecting inherent coproduction of record (Oglesby Affidavit dated March 18, 1974, paragraph 72, p. 10).

21. In the July 1964 and February 1965 interviews, Oglesby did not disclose Stephens' belief or Stephens' further belief.

22. In its fifth amendment dated March 5, 1965, responsive to the final rejection of January 19, 1965,

(DX 5, pp. 98-108) Pfizer made the February 1965 interview of record (DX 5, pp. 99, 106-107) stating that Pfizer could not state unequivocally that the "additional active entity" identified in the Stephens' prior work was not Doxycycline but that based on the Murai 1964 investigation it had concluded from the differences in ultraviolet spectra, that the "additional active entity" was not Doxycycline (DX 5, pp. 106-107). In that amendment Pfizer also offered to provide the Patent Office, upon request, with additional information respecting the experimental techniques used in the Murai 1964 investigation (DX 5, p. 107). The Patent Office did not request any further information.

In that amendment Pfizer did not state that it had identified the Stephens' applications at the July 1964 and February 1965 interviews and did not disclose Stephens' belief or Stephens' further belief.

23. Pfizer did not disclose any of the facts respecting the possible inherent coproduction of Doxycycline to the Patent Office until the July 1964 and the February 1965 interviews, and Pfizer did not make any facts respecting the possible inherent coproduction of Doxycycline in Stephens' prior work of record in the Patent Office until March 5, 1965 (DX 5, pp. 107-108).

24. Pfizer did not, at any time during the prosecution of the Doxycycline application disclose to the Patent Office Stephens' belief or Stephens' further belief which Stephens maintained from prior to the filing of the Doxycycline application and until June 1964.

25. Pfizer did not at any time during the prosecution of the Doxycycline application disclose to the Patent Office the chromatographic evidence obtained

in the Murai 1964 investigation tending to indicate that the "additional active entity" in Stephens' prior work was Doxycycline.

26. The Patent Office knew from the March 5, 1965 amendment that Pfizer obtained chromatographic data in Stephens' prior work indicating that Doxycycline might be inherently coproduced when following the process disclosed in the Stephens' applications. The Patent Office did not know from that amendment or from anything else that Pfizer disclosed to the Patent Office, that chromatographic data was also obtained in the Murai 1964 investigation which tended to indicate that Doxycycline was inherently coproduced in Stephens' prior work.

27. Examiner Adams understood the March 5, 1965 amendment to impliedly represent that there was no data resulting from the Murai 1964 investigation which tended to indicate that Doxycycline was inherently coproduced in Stephens' prior work (Adams Affidavit dated February 3, 1975, paragraph 6, p. 3).

28. Examiner Adams understood the March 5, 1965 amendment to impliedly represent that there was no data resulting from the Murai 1964 investigation which tended to indicate that Doxycycline was inherently coproduced in following the processes disclosed in the cited references or the Belgian Patent (Adams Affidavit dated February 3, 1975, paragraphs 5, 6, pp. 3-4).

29. Examiner Adams did not avail himself of Oglesby's offer in the March 5, 1965 amendment to supply additional information regarding the techniques employed in the Murai 1964 investigation and considered the information provided from the Murai 1964 investigation sufficient to establish patentability, even if inherent

coproduction had been in issue, because Examiner Adams did not know of the chromatographic data obtained in the Murai 1964 investigation and assumed that Oglesby had fairly represented the results obtained in the Murai 1964 investigation (Adams Affidavit dated February 3, 1975, paragraphs 5 and 6, pp. 3-4; Adams Affidavit dated February 24, 1975, paragraph 7, p. 7).

30. Examiner Adams did not know from the March 5, 1965 amendment or from anything else Pfizer disclosed to the Patent Office during the prosecution of the Doxycycline application either Stephens' belief or Stephens' further belief.

31. Had Pfizer disclosed to Examiner Adams that chromatographic data, tending to indicate the inherent coproduction of Doxycycline in Stephens' prior work and in following the process described in the Stephens' applications, had been obtained in the Murai 1964 investigation, and had Pfizer further disclosed Stephens' belief and Stephens' further belief, Examiner Adams would have been interested in and considered that chromatographic data material (Adams Affidavit dated February 3, 1975, paragraph 5, p. 3).

J. Conclusions of Law Concerning Pfizer's Misrepresentations to the Patent Office Respecting the Prior Inherent Coproduction of Doxycycline

1. At all times during the prosecution of the Doxycycline application Pfizer deliberately withheld from the Patent Office Stephens' belief that Doxycycline was inherently coproduced in Stephens' prior work and in following the process disclosed in the Stephens' applications, and further deliberately withheld from the Patent Office Stephens' further belief that if Doxycycline

was inherently coproduced in Stephens' prior work and in the process described in the Stephens applications, that Doxycycline was also inherently coproduced in the processes disclosed in the cited references and the Belgian Patent, which beliefs Stephens maintained from prior to the filing of the Doxycycline application and until June, 1964.

2. Pfizer had a duty to disclose Stephens' belief and Stephens' further belief to the Patent Office with reasonable diligence after the filing of the Doxycycline application and at all times thereafter during the prosecution of the Doxycycline application.

3. In the March 5, 1965 amendment reporting the results of the Murai 1964 investigation, Pfizer deliberately disclosed only the favorable ultraviolet data which indicated that inherent coproduction did not occur, which deliberately withholding the unfavorable chromatographic data obtained during the same investigation, which tended to indicate that inherent coproduction did occur.

4. Pfizer had a duty to disclose that part of the Murai 1964 investigation which tended to indicate the inherent coproduction of Doxycycline by chromatographic data in the July 1964 and February 1965 interviews and in its March 5, 1965 amendment and at all times thereafter during the prosecution of the Doxycycline application.

5. The cited references and the Belgian Patent were prior art as to the Doxycycline application under 35 U.S.C. §102.

6. Stephens' prior work and the Stephens' applications were not prior art as to the Doxycycline application under 35 U.S.C. §102.

7. Pfizer's offers to apprise the Patent Office of any further information it might request concerning the Murai 1964 investigation in the July 1964 and the February 1965 interviews and in the March 5, 1965 amendment is insufficient to satisfy Pfizer's uncompromising duty of absolute candor and full and complete disclosure. It was Pfizer's duty to disclose that in the Murai 1964 investigation chromatographic data tended to indicate inherent coproduction, and since the reported results of the Murai 1964 investigation did not indicate any contradictory data, the Patent Office had no duty to inquire further.

8. Pfizer is estopped to assert that it disclosed to Examiners Modance and Adams in the July 1964 and the February 1965 interviews that Stephens' prior work might possibly have inherently coproduced Doxycycline and that it identified the Stephens applications because Pfizer failed to state in writing and of record that it brought that information to the attention of the Patent Office in those interviews.

9. By disclosing only the possibility of inherent coproduction by chromatographic data at the time of Stephens' prior work, and by withholding Stephens' belief and Stephens' further belief, and by deliberately withholding that part of the Murai 1964 investigation which tended to indicate the inherent coproduction of Doxycycline by chromatographic data in Stephens' prior work, Pfizer deliberately withheld from the Patent Office the facts and Stephens' beliefs on which the Patent Office might have concluded that the cited references and the Belgian Patent were prior art which anticipated the Doxycycline application under 35 U.S.C. §102. Pfizer therefore deliberately withheld facts and beliefs which were material to the issue of whether

or not Doxycycline was anticipated under 35 U.S.C. §102.

10. Pfizer's deliberate withholding of Stephens' belief that Doxycycline was inherently coproduced in Stephens' prior work and Stephens' further belief that if Doxycycline was inherently coproduced in accordance with the process described in Stephens' application it was also inherently coproduced in following the processes of the cited references and the Belgian Patent and its deliberate withholding of that part of the Murai 1964 investigation which tended to indicate the inherent coproduction of Doxycycline by chromatographic data in Stephens' prior work constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all facts which may be relevant to an issue of patentability.

K. The Facts Respecting Pfizer's Withholding of Experimental Data Evidencing Its Inability to Carry Out Portions of the Patented Process

Use of a Ruthenium Catalyst

1. The Doxycycline patent application and patent states that Doxycycline and the further compounds claimed therein may be produced by the hydrogenation of certain other compounds in the presence of "noble metal" catalysts (DX 67, column 1, lines 21-30 and 51-65). The patent application and patent further identify ruthenium as one of the preferred noble metal catalysts (DX 67, column 2, lines 26-28 and 38-40).

2. The Doxycycline patent claims, in addition to Doxycycline and other related compounds, the process for producing such compounds by hydrogenating certain other compounds with "a catalytic amount of a noble metal catalyst" (DX 67, claims 1, 4 and 5).

3. Prior to filing the Doxycycline application Pfizer had been unsuccessful after a number of experiments in its efforts to use ruthenium to catalyze the hydrogenation process disclosed and claimed in the patent application and patent (DX 60, 62, 63 and 64).

4. Pfizer did not succeed in using ruthenium to catalyze the hydrogenation process disclosed and claimed in the Doxycycline patent application and patent at any time prior to or during the prosecution of the Doxycycline application (DX 65, 66 and 75).

5. Pfizer did not disclose to the Patent Office at any time during the prosecution of the Doxycycline application its unsuccessful efforts to use ruthenium to catalyze the hydrogenation process disclosed and claimed in the Doxycycline patent application and patent.

6. Had Pfizer diclosed to the Patent Office that all all times prior to the issuance of the patent it had been unsuccessful in using ruthenium in all of its experiments and had not been successful in any of its experiments in using ruthenium to catalyze the claimed hydrogenation process, Examiner Adams would have rejected at least the principal process claim (Claim 1) of the Doxycycline application under 35 U.S.C. §112 (Adams Affidavit dated February 3, 1975, paragraph 8, pp. 4-5).

Preparation of 7-Chloro-Doxycycline

7. Example XXXV of the Doxycycline patent application and patent describes a detailed procedure for the preparation of a compound known as 7-chloro-

doxycycline (7-chloro-6-epi-6-deoxy-5-oxytetracycline) by the hydrogenation of a compound known as 7-chloro-methacycline (7-chloro-6-deoxy-6-demethyl-6-methylene-5-oxytetracycline hydrochloride), and specifies the exact conditions to be used in the hydrogenation reaction (DX 5, p. 38, Example XXXV; DX 67, Example XXXV, column 18, lines 10-21).

8. The process for producing 7-chloro-doxycycline from 7-chloro-methacycline as described in Example XXXV is claimed in the Doxycycline application and patent (DX 67, Claims 1-4).

9. In March, April and May of 196', Pfizer attempted in five separate experiments to make 7-chloro-doxycycline using the process described in Example XXXV of the Doxycycline patent application and patent. In four of the five experiments the presence of only the 7-chloro-methacycline starting material was identified and 7-chloro-doxycycline as not identified. In the fifth experiment, only badly degraded materials, which could not be identified as 7-chloro-doxycycline were obtained. 7-chloro-doxycycline was not identified or isolated in any of these five experiments (DX 68-71).

10. Pfizer did not succeed in making 7-chloro-doxycycline as disclosed in Example XXXV and as claimed in the Doxycycline patent application and patent at any time prior to or during the prosecution of the Doxycycline application.

11. Pfizer did not disclose to the Patent Office at any time during the prosecution of the Doxycycline application its unsuccessful efforts to make 7-chloro-doxycycline as disclosed in Example XXXV and as claimed in the Doxycycline patent application and patent.

12. Had Pfizer disclosed to the Patent Office that at all times prior to the issuance of the patent it had been unsuccessful in making 7-chloro-doxycycline by the procedure described in Example XXXV in all of its experiments and had not been successful in any of its experiments in making 7-chloro-doxycycline by the procedure described in Example XXXV and as claimed in the Doxycycline patent application and patent, Examiner Adams would have rejected at least the principal process claim (Claim 1) of the Doxycycline application under 35 U.S.C. §112 (Adams Affidavit dated February 3, 1975, paragraph 9, p. 5).

L. Conclusions of Law Concerning Pfizer's Inability to Carry Out Portions of the Patented Process

Use of a Ruthenium Catalyst

1. From the filing date of the Doxycycline application and thereafter throughout the prosecution of the Doxycycline application Pfizer deliberately withheld from the Patent Office the fact that in all of its experiments it was unsuccessful in using ruthenium, a designated preferred catalyst, in the hydrogenation process for producing Doxycycline and the other claimed compounds disclosed and claimed in the patent application and patent.

2. Pfizer had a duty to disclose to the Patent Office with reasonable diligence after the filing of the Doxycycline application and thereafter during the prosecution of the Doxycycline application that it had never successfully used ruthenium to catalyze the hydrogenation process to produce Doxycycline or any of the other compounds claimed in the Doxycycline patent application and patent.

3. Had Pfizer disclosed to the Patent Office that during the prosecution of the Doxycycline application it had never successfully used ruthenium to catalyze the hydrogenation process to produce Doxycycline or any of the other claimed compounds, the Patent Office would have rejected at least broad claim 1 of the patent under 35 U.S.C. §112.

4. Pfizer's deliberate withholding from the Patent Office of its unsuccessful efforts to use ruthenium as a catalyst in the process disclosed and claimed in the Doxycycline patent application and patent was material to the issue of whether or not at least broad process claim 1 was patentable under 35 U.S.C. §112.

5. But for Pfizer's deliberate withholding of its unsuccessful efforts to use ruthenium to catalyze the claimed hydrogenation process, the Doxycycline patent with at least broad process claim 1 would not have issued.

6. Pfizer's deliberate withholding and concealment from the Patent Office during the prosecution of the Doxycycline application that it had never successfully used ruthenium as a catalyst constitutes inequitable conduct which does not satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all facts which may be relevant to an issue of patentability.

Preparation of 7-chloro-doxycycline

7. From the filing date of the Doxycycline application and thereafter throughout the prosecution of the Doxycycline application Pfizer deliberately withheld

from the Patent Office that in all of its experiments it was unsuccessful in making 7-chloro-doxycycline as described in Example XXXV of the specification of the Doxycycline patent application and patent and as claimed in the patent application and patent.

8. Pfizer had a duty to disclose to the Patent Office with reasonable diligence after the filing of the Doxycycline application and thereafter during the prosecution of the Doxycycline application that it had never successfully made 7-chloro-doxycycline as described in Example XXXV of the Doxycycline patent application and patent and claimed in the Doxycycline patent application and patent.

9. Had Pfizer disclosed to the Patent Office that during the prosecution of the Doxycycline application it had never successfully made 7-chloro-doxycycline as disclosed in Example XXXV and as claimed in the Doxycycline patent application and patent, the Patent Office would have rejected at least broad claim 1 of the patent under 35 U.S.C. §112.

10. Pfizer's deliberate withholding from the Patent Office of its unsuccessful efforts to make 7-chloro-doxycycline as described in Example XXXV of the Doxycycline patent application and patent and as claimed in the Doxycyline patent application and patent was material to the issue of whether or not at least the broad process claim 1 was patentable under 35 U.S.C. §112.

11. But for Pfizer's deliberate withholding of its unsuccessful efforts to make 7-chloro-doxycycline as

described in Example XXXV and as claimed in the Doxycycline patent application and patent, the Doxycycline patent with at least broad process claim 1 would not have issued.

12. Pfizer's deliberate withholding and concealment from the Patent Office during the prosecution of the Doxycycline application that it had never successfully made 7-chloro-doxycycline as described in Example XXXV constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all facts which may be relevant to an issue of patentability.

M. The Facts Respecting Pfizer's Withholding of and Misrepresentation of the Facts in this Court Concerning the Significance of the 5-Position Stereochemistry of Doxycycline During Prosecution in the Patent Office

1. Pfizer is represented of record in this proceeding by two firms of attorneys Gibson, Dunn & Crutcher (attorneys Gibson) by J. von Kalinowski, R. Cooper, and J. Martin, among others, and Cushman, Darby & Cushman by P. Kokulis and E. Martin, among others.

2. On November 9, 1973, Defendant USV filed a Request for Production of Documents seeking all of the patent prosecution files relating to the Doxycycline patent including Oglesby's prosecution files and Oglesby's internal notes and memoranda (Defendant USV's Request for Production of Documents No. 3). Pfizer responded on December 12, 1973 and refused to produce these documents on the grounds, among others, that the Request "seeks documents which are

irrelevant" (Plaintiff Pfizer's Response to Defendant USV's Request for Production of Documents No. 3).

3. On December 15, 1973 Defendant USV noticed Oglesby's deposition and informally requested Pfizer to voluntarily produce all of the Oglesby prosecution files including his internal notes and memoranda on the understanding that there would be no waiver of any claim of work product or attorney client privilege (DX 16). Pfizer refused (Oglesby deposition of March 4, 1974, p. 39).

4. During Oglesby's deposition on March 4, 1974, Pfizer's counsel J. Martin informed Defendant USV's counsel that Connolly & Hutz refused to produce certain documents from Oglesby's prosecution files, stating that such documents were Oglesby's internal memoranda (the Oglesby internal memoranda) which had never been disclosed or communicated to Pfizer, but maintained solely within Connolly & Hutz' offices, and that Connolly & Hutz regarded the Oglesby internal memoranda as its property and also protected by the attorney-client and work product privileges and refused to produce them. At that time Connolly and Hutz produced only a group of documents which consisted primarily of letters between Oglesby and Pfizer (DX 61, Oglesby deposition of March 4, 1974, pp. 32-33).

During Oglesby's deposition Mr. Hutz (Oglesby's law partner in Connolly & Hutz) stated that J. Martin's statement that the Oglesby internal memoranda had never been disclosed or communicated to Pfizer and that Connolly & Hutz regarded them as their property and protected by the attorney-client and work product privileges was correct (DX 61, Oglesby deposition, March 4, 1974, p. 39).

Both statements were made in the presence of Oglesby, Knuth and Kokulis. Knuth was present at Oglesby's deposition to assist Pfizer's counsel on technical questions (Knuth Affidavit dated April 19, 1975, paragraph 2, p. 1). Kokulis participated in the deposition for Pfizer. Knuth and Kokulis do not deny hearing those statements, although as of April 19, 1975, Knuth had no present independent recollection of those statements (Knuth Affidavit, *supra*, paragraph 2, p. 1).

During Oglesby's deposition on March 4, 1974, neither Kokulis nor Knuth said that the statements that no one outside Connolly & Hutz had seen the Oglesby internal memoranda was true or false. Rather, both remained silent on that subject.

None of the Oglesby internal memoranda were produced during Oglesby's deposition (Pfizer Brief dated April 21, 1975, p. 10).

5. Prior to his deposition on March 4, 1974, Oglesby had reviewed only the file wrapper and none of the Oglesby internal memoranda and only Hutz had reviewed Oglesby's files and deleted from the documents produced all of the Oglesby internal memoranda without reading them (Oglesby deposition March 4, 1974, p. 93; Hutz Affidavit dated April 28, 1975, paragraph 2, p. 2).

6. During his deposition on March 4, 1974, Oglesby was questioned about what transpired in his interviews with the Patent Office Examiners and Oglesby testified that his practice was to quickly prepare an amendment rather than a document and incorporate in the amendment all that transpired which was germane to the issues at hand and then file the amendment in the Patent Office. Oglesby further stated that if something

unusual occurred, which he didn't believe happened at the March 29, 1962 interview, he might have prepared a memo but did not believe he did for that interview and could recall nothing other than what was recorded in the amendment filed on April 26, 1962 (Oglesby deposition, March 4, 1974, pp. 107-108, 119).

7. During Oglesby's deposition on March 4, 1974, Pfizer's counsel J. Martin sought to stop further questioning of Oglesby about what had transpired in interviews with the Patent Office Examiners, stating that it was a waste of time since Oglesby had testified that the amendments filed in the Patent Office reflected the substance of the interviews and as contemporaneous documents were more reliable than Oglesby's recollection of events occurring 12 years ago (Oglesby deposition, March 4, 1974, p. 268).

8. During Oglesby's deposition on March 4, 1974, and in accordance with the practice in the coordinated and consolidated actions, Defendant USV's attorneys arranged a telephone conference with Pfizer's attorneys and with Special Master Heidenreich and requested him to order the production of Oglesby's internal memoranda. At that time Pfizer counsel J. Martin represented to Special Master Heidenreich that the Oglesby internal memoranda had never been transmitted to nor seen by Pfizer, or by anyone else, and that Connolly & Hutz regarded them as its property and refused to produce them (DX 81, Tr. of Heidenreich Conference call, p. 2).

9. During Oglesby's deposition on March 4, 1974, Pfizer produced a letter from Knuth to Oglesby dated July 6, 1964 (DX 20). Oglesby's handwritten notes

(upon which Pfizer subsequently sought to rely in connection with these motions) had been deleted from the bottom of that letter (the Oglesby handwritten notes) by Hutz prior to its production (DX 15; Hutz Affidavit dated April 28, 1975, paragraph 2, p. 2). Counsel for USV were not advised that the Oglesby handwritten notes had been deleted (Pfizer Brief dated April 21, 1975, p. 7).

10. The Original Motion filed on May 29, 1974 involved, *inter alia,* the charge by Defendant USV that Pfizer had not provided the Patent Office with all of the facts concerning its knowledge and beliefs as to the absolute stereochemical configuration of Doxycycline at the 5-position (USV Brief, May 29, 1974, p. 10; USV Reply Brief, p. 13).

11. In early 1974 Defendant USV spent many days taking the depositions of Pfizer's scientists and patent agents and thereafter extensively briefed the Original Motion.

12. On July 30, 1974 Pfizer filed an affidavit executed by Oglesby in opposition to the Original Motion. That affidavit did not state or indicate that during the prosecution of the Doxycycline application Pfizer had an uncertain belief as to the absolute stereochemical configuration of Doxycycline at the 5-position or that Oglesby had ever discussed 5-position stereochemistry with any of the Patent Examiners.

13. On September 11, 1974, the first day of argument on the Original Motion, Pfizer's counsel Cooper stated that the 5-position stereochemistry ". . . has at all times been irrelevant to the patentability of Doxycycline . . ." and that ". . . the whole point regarding the 5-position stereochemistry is not relevant

to the prosecution history" (Tr. September 11, 1974, pp. 111, 115).

14. On September 13, 1974, the second day of argument on the Original Motion, Pfizer's counsel Cooper for the first time disclosed that two of the Oglesby internal memoranda (the two documents) supported Pfizer's assertion to the Court that Oglesby had discussed the 5-position stereochemistry with the Patent Examiner in the March 1962 interview (Tr. September 13, 1974, pp. 182, 199).

The Court inquired whether Pfizer should be permitted to produce only selected Oglesby internal memoranda which happened to support its position.

Pfizer's counsel Cooper then stated to the Court that they had never previously seen the two documents and that Pfizer had never had or seen the two documents and that he had recently learned about the two documents in a telephone conversation with Oglesby (Tr. September 13, 1974, pp. 168-170), pp. 119-200, p. 226. (*See Also,* Tr. January 24, 1975, p. 73). Knuth was present at the September 13, 1974 hearing (Tr. September 13, 1974, p. 2), but did not state whether or not the statement that Pfizer had never seen the two documents was true or false. Rather he remained silent.

15. On September 20, 1974 Pfizer produced the two documents which relate to Oglesby's March 29, 1962 interview with Examiner Adams and indicate that Oglesby discussed the stereochemical formula depicted in the Belgian Patent at the 5-position with Examiner Adams (DX 18, 6, 12).

Pfizer's first amendment dated April 26, 1962 does not disclose that Oglesby discussed the stereochemical formula depicted in the Belgian Patent at the 5-position with Examiner Adams in the March 1962 interview.

16. On January 3, 1975 Pfizer produced another copy of the Oglesby handwritten note letter to Defendant USV containing the handwritten notes previously deleted by Hutz, together with other documents (Pfizer Brief dated April 21, 1975, pp. 8, 9). The handwritten note letter containing the handwritten notes had never been produced to the Masters (Tr. January 25, 1975, pp. 303-304). The handwritten notes relate to Oglesby's July 9, 1964 interview with Examiner Modance and indicate that Oglesby discussed the stereochemical configuration of Doxycycline at the 5-position with Examiner Modance (DX 15).

Pfizer's third amendment dated July 23, 1964 does not disclose that Oglesby discussed the stereochemical configuration of Doxycycline at the 5-position with Examiner Modance on July 9, 1964.

17. On January 24, 1975, the fourth day of oral argument on the Original Motion, Pfizer's attorneys J. Martin and E. Martin again represented that the Oglesby internal memoranda had never been produced to Pfizer or Pfizer's attorneys, and that Connolly & Hutz had just recently produced them to Pfizer's attorneys (Tr. January 24, 1975, pp. 114-117). Kokulis was present at the January 24, 1975 hearing (Tr. January 24, 1975, p. 2), but did not state whether or not the statement that the Oglesby internal memoranda had never been produced to Pfizer or Pfizer's attorneys until just recently was true or false. Rather he remained silent.

18. On January 31, 1975, the sixth day of hearings on the Original Motion, Pfizer's counsel Cooper and Oglesby disclosed for the first time that the complete Oglesby prosecution files including Oglesby's internal

memoranda were delivered to Pfizer in the summer of 1973 and at that time were reviewed by Pfizer's Knuth (Tr. January 31, 1975, pp. 313, 376-377). Kokulis was present at the January 31, 1975 hearing (Tr. January 31, 1975, p. 2), but did not state whether or not he had also reviewed the complete Oglesby prosecution files including some of Oglesby's internal memoranda in the summer of 1973. Rather he remained silent.

19. On February 5, 1975 additional documents from Oglesby's prosecution files were produced for the first time to defendants (Pfizer's Brief dated April 21, 1975, p. 10). Some of these documents (*e.g.*, DX 8, 10) relate to Pfizer's uncertainty concerning the absolute stereochemistry at the 5-position. A handwritten note (DX 19) in these files stated that some of the Oglesby prosecution files, described on the note as "drafts", had been delivered to Pfizer on February 27, 1974, five days before the commencement of Oglesby's deposition.

20. On February 13, 1975 the Present Motion was filed by the I.R. Defendants and by Defendant USV.

21. On April 20, 1975, Kokulis disclosed for the first time that in August of 1973 he had received the Connolly & Hutz files from Pfizer and reviewed them and was aware that they contained "some memoranda" (Kokulis Affidavit dated April 20, 1975, paragraphs 2, 3, p. 1).

22. The two documents first produced on September 20, 1974, the Oglesby handwritten notes first produced on January 3, 1975, and the documents from the Oglesby prosecution files first produced on February 5, 1975 revealed for the first time that Pfizer was concerned from the date of the filing of the Doxycycline

application until at least June 1964 that the Belgian Patent might be a complete anticipation of Doxycycline, or at least might limit Pfizer to product-by-process claims, because of its belief that the Belgian Patent depicted the absolute stereochemical configuration of Doxycycline at the 6-position, its uncertain belief that the Belgian Patent did not depict the absolute stereochemical configuration of Doxycycline at the 5-position, and Oglesby's uncertainty until June, 1964 whether the Patent Office would follow the *Le Grice* and *Brown* decisions and thus disregard the stereochemical formula depicted in the Belgian Patent as an anticipation under 35 U.S.C. §102 or alternatively would limit Pfizer to product-by-process claims.

N. Conclusions of Law Concerning Pfizer's Concealment and Misrepresentation of Facts in this Court

1. From the filing of the within action and until January 31, 1975, Pfizer deliberately concealed from attorneys Gibson that in the summer of 1973 Pfizer's Knuth had received and reviewed Oglesby's prosecution files including all of the Oglesby internal memoranda.

2. From the filing of the within action and until April 20, 1975, Kokulis deliberately concealed from attorneys Gibson that in August of 1973 he had received and reviewed Oglesby's prosecution files including some of the Oglesby internal memoranda.

3. From at least December 12, 1973 and until January 31, 1975, Pfizer through its attorneys Gibson and its patent agent Knuth deliberately concealed from the Court that 11 of the Oglesby internal memoranda were delivered to and reviewed by Pfizer's Knuth in the summer of 1973.

4. From at least December 12, 1973 and until January 31, 1975 Pfizer through its attorneys Gibson and its patent agent Knuth deliberately misrepresented, expressly and by its silence, to the Court that Pfizer had not received or reviewed all of the Oglesby internal memoranda in the summer of 1973.

5. From at least December 12, 1973 and until April 20, 1975 Kokulis deliberately concealed from the Court that some of Oglesby's internal memoranda were delivered to and reviewed by him in August of 1973.

6. From at least December 12, 1973, and until April 20, 1975 Kokulis deliberately misrepresented, by his silence, to the Court that he had not received or reviewed some of Oglesby's internal memoranda in August of 1973.

7. Pfizer and Kokulis had a duty to inform the Court, at least as early as March 4, 1974, that they had received and reviewed all or some, respectively, of the Oglesby internal memoranda in the summer of 1973.

8. Prior to Oglesby's deposition on March 4, 1974, Hutz removed Oglesby's handwritten notes from the July 6, 1964 letter with deliberate and reckless disregard about revealing the true and complete facts.

9. Prior to his deposition on March 4, 1974, Oglesby deliberately and with reckless disregard about revealing the true and complete facts, failed to review his internal memoranda, and as a consequence, erroneously testified that he did not believe that he had made any file memoranda concerning the Doxycycline application, and that the amendments filed in the Patent Office stated the substance of his interviews with the Examiners.

10. On July 30, 1974 Oglesby with deliberate and reckless disregard for the true and complete facts, misrepresented to the Court that the stereochemical formula depicted in the Belgian patent at the 5-position was irrelevant to any issue of patentability during the prosecution of the Doxycycline application.

11. On September 11, 1974, Pfizer, through its attorneys Gibson, deliberately misrepresented to the Court that the stereochemical formula depicted in the Belgian Patent at the 5-position was always irrelevant to any issue of patentability during the prosecution of the Doxycycline application.

12. The deliberate misrepresentations, by expression or by silence, and the acts of Knuth, Oglesby, Hutz, Cooper, J. Martin, Kokulis and E. Martin are imputed to Pfizer.

13. Pfizer's and Kokulis' deliberate concealments and misrepresentations, Oglesby's and Hutz' deliberate and reckless disregard about revealing the true and complete facts, and Pfizer's and Oglesby's deliberate misrepresentations that the absolute stereochemistry of Doxycycline at the 5-position was always irrelevant to any issue of patentability delayed production of the two documents until September 20, 1974, delayed production of the handwritten notes until January 3, 1975, and delayed the production of the documents from the Oglesby prosecution files until February 5, 1975.

14. The two documents first produced on September 20, 1974, the Oglesby handwritten notes first produced on January 3, 1975, and the documents from the Oglesby prosecution files first produced on February 5, 1975 revealed for the first time that Pfizer was

concerned from the date of the filing of the Doxycycline application on May 5, 1961 until at least June 1964 that the Belgian Patent might be a complete anticipation of Doxycycline under 35 U.S.C. §102, or at least might limit Pfizer to product-by-process claims under 35 U.S.C. §112.

15. Pfizer's and Kokulis' deliberate concealments and misrepresentations, Oglesby's and Hutz' deliberate and reckless disregard about revealing the true and complete facts and Pfizer's and Oglesby's deliberate misrepresentation that the absolute stereochemistry of Doxycycline at the 5-position was always irrelevant to any issue of patentability were material to the issue of whether or not Doxycycline was anticipated under 35 U.S.C. §102 and whether or not Pfizer would be limited to product-by-process claims under 35 U.S.C. §112, and were also material to the issues presented by the Original Motion, and therefore Pfizer's and Kokulis' conduct constitutes fraud on the Court, unclean hands and inequitable conduct.

16. Attorneys Gibson conduct did not intentionally commit fraud on the Court.

O. Conclusions of Law Concerning Pfizer's Overall Course of Conduct Before the Patent Office

From the time of the filing of the Doxycycline application and thereafter throughout the prosecution thereof Pfizer deliberately embarked upon a course of conduct to withhold from or to misrepresent to the Patent Office prior art and facts which were material to the issues of whether or not Doxycycline was anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. §103 or whether or not Pfizer was entitled

to claims of the broad scope solicited and obtained under 35 U.S.C. §112, all as set forth in the preceding Conclusions of Law. That entire course of conduct, taken as a whole, constitutes fraudulent conduct, or at the very least a calculated recklessness about the truth for the purpose of obtaining a patent containing the broadest possible product and process claims. Pfizer's entire course of conduct, taken as a whole, also constitutes inequitable conduct which fails to satisfy an applicant's uncompromising duty of absolute candor and full and complete disclosure to the Patent Office of all facts which may be relevant to an issue of patentability.

P. Conclusions of Law Applicable to Each of the Above Lettered Sections of the Conclusions of Law

1. The knowledge, beliefs and acts of each of the named inventors on the Doxycycline application, and the knowledge, beliefs and acts of Pfizer's patent agent Knuth and Pfizer's scientists English, McBride, Frost, Woodward, von Wittenau, Kent, Conover and Murai is imputed to Oglesby and the knowledge, beliefs and acts of all of the aforementioned persons is imputed to Pfizer.

2. Pfizer's conduct in withholding from and in misrepresenting to the Patent Office prior art facts and beliefs which were material to the issues of whether or not Doxycycline was anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. §103, or whether or not Pfizer was entitled to claims of the broad scope solicited and obtained under 35 U.S.C. §112 was material to the question of whether or not the Patent Office might have stricken the Doxycycline application under Patent Office Rule 56.

Q. Pfizer's Requests for Admissions

Pursuant to Rule 36, Fed.R. Civ. P., Pfizer has made extensive requests for admissions which it claims are germane to this motion. For the reasons stated in the law section herein the admissions sought are irrelevant to this motion.

R. Ultimate Conclusion of Law

The Doxycycline patent is invalid and unenforceable.

Let Judgment Be Entered Accordingly,

/s/ Miles W. Lord

Miles W. Lord

United States District Judge

JULY 16, 1975

Appeal From the United States District Court for the District of Minnesota.

United States Court of Appeals for the Eighth Circuit.

In re: Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions. Pfizer, Inc., Appellant, v. International Rectifier Corp., Rachelle Laboratories Italia, S.p. A., Rachelle Laboratories, Inc., Rachelle Pharmaceuticals International, S.A., and USV Pharmaceutical Corp., Appellees. No. 75-1695.

Submitted: March 9, 1976

Filed: June 16, 1976

Before GIBSON, Chief Judge, HEANEY and WEBSTER, Circuit Judges.

GIBSON, Chief Judge.

This patent infringement case was initially filed by Pfizer, Inc. seeking damages and declaratory and injunctive relief in the Central District of California. The defendants, International Rectifier Corp. (IRC)[1]

[1]International Rectifier Corp. and its four subsidiaries, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc.,

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and USV Pharmaceutical Corp. (USV), answered, pleading that Pfizer's United States Patent No. 3,200,-149[2] is invalid and unenforceable for failure to meet statutory requirements of patentability and for fraud and misconduct before the Patent Office. Both defendants at first admitted infringement but subsequently amended their answer to deny infringement and assert unfair competition and antitrust counterclaims. Upon defendants' motion, the case was transferred to the United States District Court for the District of Minnesota and assigned to District Judge Miles W. Lord for coordinated pretrial proceedings with IRC's antitrust case and other antibiotic antitrust litigation, by order of the Judicial Panel on Multidistrict Litigation dated March 12, 1973. The case is scheduled to be returned to the Central District of California for trial after completion of coordinated pretrial proceedings.

While the case was pending for pretrial processing, defendants filed successive motions for partial summary judgment maintaining that Pfizer's conduct in prosecuting the patent application before the Patent Office, from the time the application was filed in May, 1961, until the patent was issued in August, 1965, constituted fraud, inequitable conduct and unclean hands, and that Pfizer's conduct before the District Court from 1973 until 1975 was also fraudulent and inequitable, separately justifying refusal to enforce the patent.

Rachelle Pharmaceuticals International, S.A., and Rachelle Laboratories (Philippines), Inc., are hereafter referred to jointly as IRC.

[2]U.S. Patent No. 3,200,149 was issued on August 10, 1965, for a chemical compound, and the process of producing the compound, called doxycycline (Pfizer tradename Vibramycin), a member of the tetracycline family of broad spectrum antibiotic drugs.

On July 16, 1975, in an extensive memorandum opinion, the District Court granted partial summary judgment and declared Pfizer's doxycycline patent invalid and unenforceable. *Pfizer, Inc. v. International Rectifier Corp.*, 186 U.S.P.Q. 511 (D.Minn. 1975). The court set forth more than 150 "uncontroverted" facts from the record of documents[3] and testimony taken in eleven days of hearings on the summary judgment and related discovery motions conducted intermittently from September, 1974, through April, 1975.

On these 150 facts, deemed uncontroverted, Pfizer was found guilty of five acts of inequitable conduct before the Patent Office, each of which, standing alone, the court considered sufficient to bar enforcement of the patent. They are: (1) Pfizer's alleged failure to disclose both the existence of, and its inability to distinguish, a prior Belgian patent of a similar compound, in order to avoid Patent Office rejection for anticipation (lack of "novelty") under 35 U.S.C. § 102 (1964)[4] and "obviousness" under 35 U.S.C. §

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[3]Pfizer opposed the motion with various memoranda, 54 exhibits and 24 affidavits. The affidavits were prepared by Patent Examiner Adams, one of three Examiners (Adams, Berg and Modance) who examined and allowed the doxycycline patent, scientists employed by Pfizer, Pfizer managers, outside patent counsel and outside legal counsel.

The defendants supported their motion with memoranda and one affidavit of Examiner Adams, otherwise relying upon Pfizer's documents, deposition testimony of Pfizer's representatives, and the official prosecution record of the patent in the Patent Office, called the "file wrapper."

[4]35 U.S.C. § 102 states in relevant part as follows:

Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed pub-

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103 (1964);[5] (2) Pfizer's argument of an allegedly false and misleading analogy between doxycycline and certain prior art epimers,[6] similarly to avoid rejection for anticipation and obviousness; (3) Pfizer's alleged concealment of test data concerning the antibacterial activity of doxycycline, with similar motivation; (4) Pfizer's alleged concealment of its scientists' beliefs that doxycycline may have been coproduced in prior art processes, similarly motivated; and (5) Pfizer's alleged concealment of repeated experimental failures of processes described and claimed in the doxycycline patent with the motive of obtaining claims broader than permissible under 35 U.S.C. § 112 (1964).[7]

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lication in this or a foreign country, before the invention thereof by the applicant for patent, or

* * *

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.

[5]35 U.S.C. § 103 states in relevant part as follows:

Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[6]The term "epimer" is defined in part IIA., *infra*.

[7]35 U.S.C. § 112 states in relevant part as follows:

Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best

Additionally, Pfizer's entire course of conduct before the Patent Office *was characterized as fraudulent* or "at the very least a calculated recklessness about the truth" for the purpose of obtaining as broad a patent as possible. Finally, Pfizer was summarily found guilty of concealing critical facts from the court, amounting to inequitable conduct and fraud on the court, that independently justified refusal to enforce the doxycycline patent.

On this appeal, Pfizer challenges the District Court's rulings as violative of the cardinal principle that summary judgment is permitted only if there is "no genuine issue as to any material fact," Fed. R. Civ. P. 56(c), and also the court's interpretation of the principles of law governing the patent infringement defense of unclean hands resulting from fraud or inequitable conduct by the patentee before the Patent Office and the District Court. Pfizer contends that the court resolved bitterly disputed issues of material fact, drew inferences unfavorable to the nonmovant and determined credibility without affording Pfizer a trial by jury in the Central District of California as demanded in its pleadings.[8]

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mode contemplated by the inventor of carrying out his invention.

* * *

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material or acts described in the specification and equivalents thereof.

[8]We express no view concerning Pfizer's asserted entitlement to a jury trial on its claim of infringement or on the defendants' assertions of patent invalidity and nonenforceability on equitable grounds. See *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 510-11 (1959); Annot., 18 A.L.R. Fed. 690 (1974).

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We think the court erred in granting partial summary judgment, as genuine issues of material fact remain as to each of Pfizer's five alleged acts of misconduct before the Patent Office, and the record does not reveal sufficient misconduct by Pfizer before the District Court in the pretrial proceedings to warrant a finding of fraud on the court and the imposition of a sanction of such severity. We express no opinion as to Pfizer's conduct before the Patent Office nor on the merits of the legal and factual issues of patent validity. The scientific issues at stake are of such moment that all parties should be permitted to present their evidence fully in a plenary trial not restricted to a trial by affidavit.[9]

I. PROPRIETY OF SUMMARY JUDGMENT.

The standards to be applied in ruling upon a motion for summary judgment pursuant to Fed. R. Civ. P. 56(c) have been clearly stated by the United States Supreme Court:

The sole issues raised in this appeal are the propriety of determining the enforceability of the doxycycline patent summarily prior to *any* plenary trial, and whether Pfizer's conduct before the District Court merited the severe sanction.

[9]We express no view of the facts sought to be established in Pfizer's 170 requests for admission by the defendants filed pursuant to Fed. R. Civ. P. 36 on March 17 and 19, 1975. The defendants did not file a response to the requests within 30 days. On April 21, 1975, the District Court ordered them answered in an additional 45 days. Thereafter, on the due date, the defendants filed an objection to all the requests as "burdensome and harassing" and suggested that partial summary judgment in their favor would moot the need for any response. Ultimately, the District Court held the requested admissions "irrelevant" and granted summary judgment for defendants declaring the patent invalid and unenforceable.

As all the facts will have to be established on remand, it will also be necessary for the District Court to reexamine its position concerning Pfizer's requests for admissions.

> Summary judgment should be entered only when the pleadings, depositions, affidavits, and admissions filed in the case "show that * * * there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), Fed. Rules Civ. Proc.

Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464, 467 (1962).

To obtain a summary judgment, the movant must demonstrate the absence of any genuine issue of material fact, and the evidence submitted to the court "must be viewed in the light most favorable to the opposing party." *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970). Movant must show "his right to a judgment with such clarity as to leave no room for controversy and that the other party is not entitled to recover under any discernible circumstances." *Ozark Milling Co. v. Allied Mills, Inc.*, 480 F.2d 1014, 1015 (8th Cir. 1973); *accord, Cervantes v. Time, Inc.*, 464 F.2d 986, 993 (8th Cir. 1972), *cert. denied*, 409 U.S. 1125 (1973). In determining whether a genuine issue of material fact exists, the court must give the nonmoving party the benefit of all reasonable factual inferences, *Adickes v. S. H. Kress & Co., supra* at 158-59; *McSpadden v. Mullins*, 456 F.2d 428 (8th Cir. 1972), and must do so without assessing credibility. *United States v. United Marketing Association*, 291 F.2d 851, 853-54 (8th Cir. 1961). Summary judgment is to be used not as a substitute for trial, but only when "it is quite clear what the truth is [and] that no genuine issue remains for trial." *Sartor v. Arkansas Natural Gas Corp.*, 321 U.S. 620, 627 (1944).

Summary judgment is notoriously inappropriate for determination of claims in which issues of intent, good faith and other subjective feelings play dominant roles. *White Motor Co. v. United States,* 372 U.S. 253, 259 (1963); *Louis Schlesinger Co. v. Kresge Foundation,* 388 F.2d 208, 212 (3d Cir.), *cert. denied,* 391 U.S. 934 (1968); *Severson v. Fleck,* 251 F.2d 920, 924 (8th Cir. 1958); 6 J. Moore, *Federal Practice* ¶56.17 [41.-1] (2d ed. 1976). Here matters of intent, good faith and credibility, have been resolved by the court in a summary proceeding. The defendants are unable to cite any Court of Appeals decision approving a summary judgment invalidating or refusing to enforce a patent on grounds of fraud or inequitable conduct before the Patent Office.[10] This court has long held the view that summary judgment is ordinarily inappropriate for disposition of patent cases in which issues of fact predominate and the requirements of Rule 56(c) are rarely met. *Long v. Arkansas Foundry Co.,* 247 F.2d 366, 369 (8th Cir. 1957). The impropriety of summary judgment in the instant case is compounded for the reason that forfeiture of the patent is sought on the basis of the patentee's personal misconduct in procuring the patent as well as technical and scientific fact.

II. THE DEFENSE OF MISCONDUCT BEFORE THE PATENT OFFICE.

The principle that a defendant in a patent infringement action may interpose as a complete defense the patentee's failure to deal candidly with the Patent Office

[10]The lower court cases cited by the defendants, *Interlego, A. G. v. F.A.O. Schwartz, Inc.,* 187 U.S.P.Q. 580 (N.D.Ga. 1975), and *Farmer Brothers Co. v. Coca-Cola Co.,* 384 F.Supp. 595 (C.D.Cal. 1974), are distinguishable and not controlling.

is a corollary of the equitable doctrine of unclean hands. *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.,* 324 U.S. 806, 814 (1945). The Supreme Court has set forth the duty of candor owed by a patent applicant as follows:

> Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an *uncompromising duty* to report to it all facts concerning possible fraud or inequitableness underlying the applications at issue. * * * Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can the agency act to safeguard the public in the first instance against fraudulent patent monopolies.

Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., supra at 818. (Emphasis added.)

The equitable origins of this doctrine, combined with recognition of the growing administrative burden facing the Patent Office, have led to expansion of the defense in recent years to encompass also a wide variety of inequitable conduct short of common law fraud or deceit.[11] *See, e.g., Monsanto Co. v. Rohm & Haas*

[11]The cases have distinguished between *fraud,* which invalidates the patent, and *inequitable conduct* which is said to render the patent unenforceable rather than invalid. However, in an infringement action involving misconduct in patent procurement the distinction carries little practical significance as under either theory the patent monopoly is terminated if sufficient misconduct is proved. *Timely Products Corp. v. Arron,* 523 F.2d 288, 297-98 (2d Cir. 1975). It has been suggested that

(This footnote is continued on next page)

Co., 456 F.2d 592, 599 (3d Cir.), *cert. denied*, 407 U.S. 934 (1972).

In the instant case, the District Court adopted a far-reaching interpretation of the doctrine, emanating from what the court described as an obligation on Pfizer's part to disclose to the Patent Office any fact that "may be relevant to an issue of patentability." Further, the court held that the defendants in proving Pfizer's breach of this obligation were not required to prove that Pfizer intended to deceive the patent examiners, and that Pfizer's claims of good faith are immaterial and do not create genuine issues of fact. We believe this interpretation imposes an unworkable standard of conduct upon the patent applicant and expands the inequitable conduct defense beyond legitimate limits.[12]

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a stronger showing of materiality of the information undisclosed or misstated is required to prove fraud than to prove inequitable conduct. *Id.* We express no view of the standards of materiality applicable under either theory.

[12]The reasons for rejecting such a broad standard were well stated by District Judge Mansfield in *Xerox Corp. v. Dennison Mfg. Co.*, 322 F.Supp. 963, 968 (S.D.N.Y. 1971):

> [T]o deny enforcement as a matter of law merely because of an innocent or good faith non-disclosure would go beyond what is necessary to protect the public against the improvident granting of a monopoly. Such a standard could also have the harmful effect of forcing a patent solicitor to flood the Patent Office in each case with a mass of data of doubtful materiality rather than take the risk that an inventor might later be denied the fruits of his monopoly because of failure to reveal some fact later magnified out of proportion by an infringer seeking to escape the reach of the patent by combing the inventor's files under our liberal pretrial discovery procedures and dredging up new-found "facts."

See also Becton Dickinson & Co. v. Sherwood Medical Industries, Inc., 516 F.2d 514, 524 (5th Cir. 1975); *Schnadig Corp. v. Gaines Mfg. Co.*, 494 F.2d 383, 393 (6th Cir. 1974).

In correcting the District Court's interpretation of the law governing this defense we express no view of Pfizer's conduct before the Patent Office or the merits of the defendants' claims.

It would be unwise to attempt to formulate a standard of conduct setting forth all elements of the defense embracing all misconduct before the Patent Office that might justify refusal to enforce a patent. However, we note that the standard is not one of strict liability for innocent or even negligent omissions or misstatements before the Patent Office. *Schnadig Corp. v. Gaines Manufacturing Co.*, 494 F.2d 383, 393 (6th Cir. 1974). Rather, to result in refusal to enforce a patent, the misconduct must be accompanied by "some element of wrongfulness, willfulness, or bad faith." *Parker v. Motorola, Inc.*, 524 F.2d 518, 535 (5th Cir. 1975); *see Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814-15 (1945) (a "willful act * * * which rightfully can be said to transgress equitable standards of conduct"). This requirement of proof has been uniformly applied in infringement actions by a majority of the circuits to claims of both fraud[13] and

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[13]*Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 598, 601 n. 14 (3d Cir.), *cert. denied*, 407 U.S. 934 (1972); *Kolene Corp. v. Motor City Metal Treating, Inc.*, 440 F.2d 77, 83 (6th Cir.), *cert. denied*, 404 U.S. 886 (1971); *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204-05 (7th Cir. 1970), *cert. denied*, 401 U.S. 913 (1971); *Norton v. Curtiss*, 433 F.2d 779, 793-95 (C.C.P.A. 1970) (interference proceeding to challenge priority of invention and strike application for fraud); *see Acme Precision Products, Inc. v. American Alloys Corp.*, 484 F.2d 1237, 1239-40 (8th Cir. 1973) (infringement claim dismissed due to deliberate misrepresentations and patentee's knowledge of fraudulent procurement); *Cataphote Corp. v. DeSoto Chemical Coatings, Inc.*, 450 F.2d 769, 772 (9th Cir. 1971), *cert. denied*, 408 U.S. 929 (1972) (antitrust counterclaim alleging fraud); *Nashua Corp. v. RCA Corp.*, 431 F.2d 220, 227 (1st Cir. 1970) (claim for refund of royalties due to fraud in procurement); *Triumph Hosiery Mills, Inc. v. Alamance Industries, Inc.*, 299 F.2d 793, 796 (4th Cir.), *cert. denied*, 370 U.S. 924 (1962); *Edward Valves, Inc. v. Cameron Iron Works, Inc.*, 286 F.2d 933, 947, *modified on other grounds*, 289 F.2d 355 (5th Cir.), *cert. denied*, 368 U.S. 833 (1961); *Haloro, Inc. v. Owens-Corning Fibreglas Corp.*, 266 F.2d 918 (D.C. Cir. 1959).

lesser inequitable conduct.[14] Moreover, proof of misconduct under either theory must be established by "clear, unequivocal and convincing" evidence. *United States v. American Bell Telephone Co.*, 167 U.S. 224, 251 (1897); *accord, Schnadig Corp. v. Gaines Manufacturing Co., supra* at 392; *Monsanto Co. v. Rohm & Haas Co., supra* at 601 n. 14.

Before summarizing the unresolved issues of fact relating to Pfizer's alleged misconduct before the Patent Office, we briefly review some undisputed background to facilitate understanding of the issues.

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[14]*Parker v. Motorola, Inc., supra* at 535; *Schnadig Corp. v. Gaines Mfg. Co.*, 494 F.2d 383, 393 (6th Cir. 1974); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 598, 601 n. 14 (3d Cir.), *cert. denied*, 407 U.S. 934 (1972); *Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp.*, 443 F.2d 867, 882 (2d Cir. 1971); *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204-05 (7th Cir. 1970), *cert. denied*, 401 U.S. 913 (1971); *see Haloro, Inc. v. Owens-Corning Fibreglas Corp.*, 266 F.2d 918 (D.C.Cir. 1959); *Norton v. Curtiss*, 433 F.2d 779, 795-96 (C.C.P.A. 1970). *See also Iron Ore Co. v. Dow Chemical Co.*, 500 F.2d 189, 195 (10th Cir. 1974); Carney, Misrepresentations Before the Patent Office: Antitrust and Other Legal Effects, 12 B.C. Ind. & Com. L. Rev. 1005 (1971).

Defendants' contention that willfulness or a similar state of mind need not be proved to render misconduct sufficiently inequitable to vitiate a patent is not supported by *Monsanto Co. v. Rohm & Haas Co., supra; Beckman Instruments, Inc. v. Chemtronics, Inc.*, 428 F.2d 555, *duplicate report at* 439 F.2d 1369 (5th Cir.), *cert. denied*, 400 U.S. 956 (1970); and *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chemical Corp.*, 407 F.2d 288 (9th Cir. 1969), upon which they rely. In *Monsanto*, the court found that knowingly false statements were made to the Patent Office and material facts deliberately concealed that would otherwise have resulted in denial of the patent. 456 F.2d at 595, 601 n. 14. Similarly, in *Beckman Instruments*, the court found that knowledge of the prior art was deliberately withheld and would have resulted in denial of the patent. 428 F.2d at 560, 564-65. And in *Monolith Portland*, a deliberate withholding of crucial information that would also have resulted in denial of the patent was recognized to justify an award of attorneys fees under the "exceptional cases" rule of 35 U.S.C. § 285. 407 F.2d at 294-97.

A. Terminology and Background.

Doxycycline is derived by synthesizing a fermentation produced drug called oxytetracycline (Pfizer tradename Terramycin) with a process called hydrogenolysis. A significant concern to Pfizer in patenting doxycycline was the prior existence of another compound of nearly identical chemical structure. This prior discovery, referred to as the McCormick compound, was produced in the 1950's by Dr. J. R. D. McCormick for American Cyanamid, and independently by Drs. Stephens and Conover, working for Pfizer, using the same process of hydrogenating oxytetracycline. It was patented by Dr. McCormick in Belgium in 1959.

All three chemical compounds are molecules consisting of component groups of atoms, called substituents, in a configuration unique to each compound. Chemists are able to describe three dimensionally the molecular structure of each compound using the terminology of stereochemistry. The special arrangement of a molecule's substituents is known as its stereochemical configuration or orientation. By convention, the various positions (asymmetric centers) on the basic molecule common to the compounds of the tetracycline family have been assigned numbers. (See Fig. 1.) One can distinguish a particular compound by referring to its stereochemical configuration at one or more individually numbered positions on the molecule.

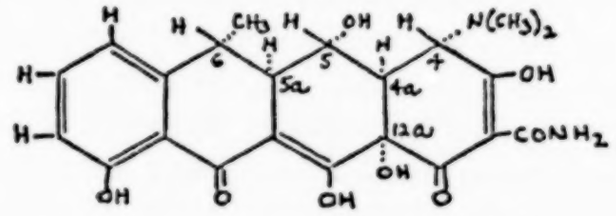
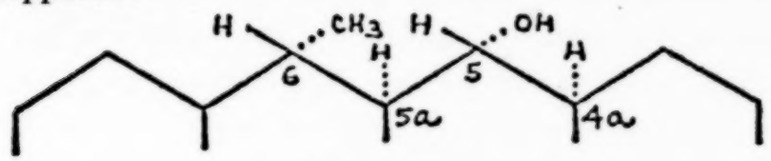
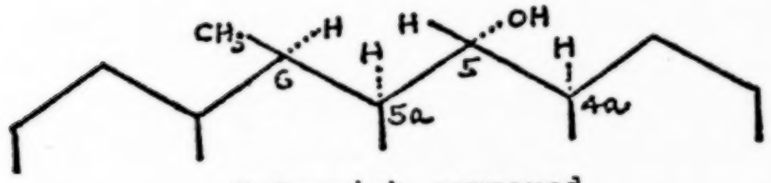


Figure 1. The complete doxycycline molecule.

If two compounds are identical at all but a single position at which one compound has a configuration opposite that of the other, the two compounds are known as "epimers" of one another. Doxycycline and the McCormick compound are 6-position epimers of each other. That is, the chemical structure of doxycycline is identical to that of the McCormick compound except at the 6-position, where their structures are opposite:



Doxycycline



McCormick compound

Figure 2. Comparison of the 6-positions of Doxycycline and the McCormick compound.

In the above diagrams, the substituents shown with dotted lines are on one side of the molecule (referred to as "down"), and those shown with solid lines are on the other side (referred to as "up").

This close structural similarity between any two compounds can pose a problem in patent prosecution. Under the Patent Act, 35 U.S.C. § 103, the existence of the second discovered epimer is presumed to be "obvious," and hence unpatentable, absent a showing that it has unexpected beneficial properties. *See generally* Note, Standards of Obviousness & the Patentability of Chemical Compounds, 87 Harv. L. Rev. 607 (1974).

Further problems can result if the evidence suggests that the second-discovered compound was previously coproduced (as a byproduct) or otherwise disclosed in the prior art so as to defeat its "novelty" within the meaning of 35 U.S.C. § 102.

B. Pfizer's Alleged Misconduct Before the Patent Office.

1. *The Belgian Patent.*

Pfizer is accused of fraud and inequitable conduct in connection with its failure in May, 1961, upon filing the doxycycline application, to cite to the Patent Office the prior art Belgian patent. In the application, Pfizer referred to the compounds of the prior art as the "known 6-deoxy-tetracyclines," without citing Dr. McCormick's Belgian patent. Pfizer's motivation for doing so, according to the defendants, was to mislead the Patent Office in order to avoid two issues of patentability: "anticipation" of Pfizer's compound by McCormick under 35 U.S.C. § 102, and the possible limitation of the doxycycline patent to "product-by-process" claims under 35 U.S.C. § 112.[15]

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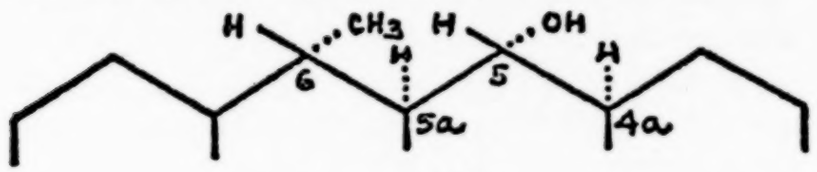
[15]A "product-by-process" claim is a form of *product* patent for a compound that cannot be described other than by reference to the process of making it. P. Rosenberg, *Patent Law Fundamentals* 76 (1975). It is substantially narrower and less desirable than the broad product claims, covering hundreds of compounds, in the doxycycline patent.

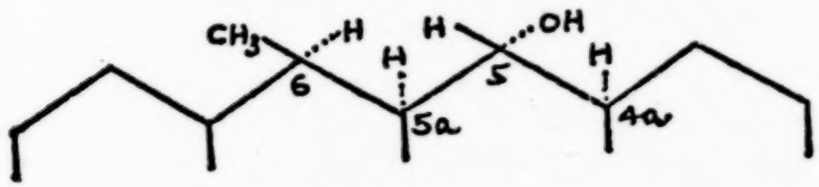
Defendants contend that because Pfizer admittedly did not know the structure of doxycycline when it filed the application, Pfizer should have referred to the prior art as the "known 6-deoxy-tetracyclines, the structure of which has not been fully established." Pfizer, they contend, experienced the same problem in its prior tetracycline patent application and should have known that it could overcome patent office rejection, as it had before, by truthful and complete disclosure. Instead, the defendants contend, Pfizer intentionally suppressed the prior art to avoid disclosing its ignorance of the structure of doxycycline and resultant inability to distinguish the prior art.

The Belgian patent contains a diagram that purports to show the stereochemical configuration common to compounds such as McCormick's. According to the defendants, Pfizer suspected that the diagram in the Belgian patent did not correctly depict the McCormick compound. Defendants concede that regardless of the inaccuracy of the diagram's depiction of the McCormick compound, Pfizer was confident that its new compound, doxycycline, had a 6-position configuration opposite that of the McCormick compound.[16] However, defendants maintain that this would not necessarily excuse Pfizer's failure to cite the Belgian patent for the reason that according to the *Von Bramer* doctrine, then in

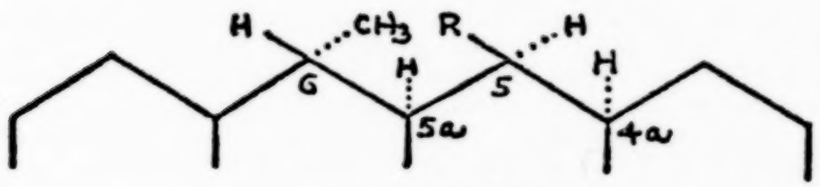
[16]Pfizer's diagrams compare the compounds in part as follows:



Doxycycline



McCormick compound



Belgian diagram

effect in the Patent Office, but later overruled,[17] the Belgian *diagram* alone could have served as a complete anticipation of doxycycline even if its illustration of doxycycline was only accidental. Thus, defendants maintain that, in view of Pfizer's concession that upon filing the application it believed the Belgian diagram correctly, albeit accidentally, depicts doxycycline at the 6-position, Pfizer knew it needed another distinction between doxycycline and the *diagram* to avoid the problem of anticipation.

Pfizer maintains it then believed, and has since confirmed, that the diagram differs from doxycycline at the 5-position despite their identity at the 6-position. Thus, Pfizer contends, in 1961 it believed the Belgian patent did not accurately depict *either* the McCormick compound (different at the 5- and 6-positions) or doxycycline (different at the 5-position). Pfizer insists the Belgian diagram was not a true *Von Bramer* anticipation and need not have been cited to the patent examiners; however, Pfizer contends that if it erred in failing to cite the Belgian patent initially as prior art, its mistake was later cured by full disclosure to the patent examiners in oral interviews during the prosecution—well after the demise of the *Von Bramer* doctrine rendered the entire matter immaterial to patentability.

[17]Under *In re Von Bramer*, 127 F.2d 149, 151 (C.C.P.A. 1942), before being modified in *Application of LeGrice*, 301 F.2d 929, 942 (C.C.P.A. 1962), and sharply limited in *Application of Brown*, 329 F.2d 1006, 1009-11 (C.C.P.A. 1964), a prior art diagram depicting the structure of a later-produced compound, even accidentally, could serve as a complete anticipation precluding patentability under 35 U.S.C. § 102(a). In the instant case, the District Court concluded that the patent examiners did not believe until June, 1964, that *Von Bramer* had been effectively overruled. Pfizer disputes this finding, and maintains that the correct date is May, 1962.

The District Court held that these later unrecorded oral disclosures were inadequate to cure Pfizer's breach of candor to the Patent Office and concluded that regardless of the later demise of the *Von Bramer* doctrine, rendering the Belgian diagram immaterial, Pfizer's initial failure to disclose its uncertainty concerning the difference between the Belgian diagram and doxycycline estops it from relying upon later disclosures in defense of its conduct.[18] The court concluded that Pfizer's deliberate initial failure to disclose the Belgian patent and delay thereafter in doing so were inequitable, and alternatively that even without the estoppel, Pfizer's deliberate delay alone of almost one year was sufficient to justify forfeiture of the patent.

However, despite the court's characterization of facts supporting these conclusions as "uncontroverted," we believe genuine issues of material fact remain as to the states of mind of Pfizer's scientists and patent counsel, precluding summary judgment, and that additional issues of technical fact are present that are unsuited for summary resolution without the benefit of live expert testimony and cross-examination in a plenary trial.

2. The False Analogy to Prior Art Epimers.

Pfizer also is accused of misconduct in connection with its response to Patent Office rejection of doxycycline as an "obvious" routine development in the art unpatentable because closely similar to the McCormick compound and lacking any unexpected beneficial properties. In its application, Pfizer described doxy-

[18]According to Pfizer, such disclosures took place in March, 1962, March, 1963, April, 1964, and July, 1964.

cycline as an epimer of the prior art McCormick compound, differing only in that the latter had an opposite configuration at the 6-position. Then, in response to Patent Office rejection, according to the defendants, Pfizer argued that the epimer doxycycline was *not* obvious because, *inter alia,* the superiority of its antibacterial properties, compared with the properties of the McCormick compound, was an *unexpected departure* from the norm of prior art epimers of tetracycline antibiotics that revealed lower activity than their epimer counterparts. This analogy, the defendants contend, was falsely drawn to deliberately confuse and mislead the patent examiners. The basis for this allegation is that Pfizer knew doxycycline had the same 6-position structure as the conventional, or "normal" form of tetracyclines (such as oxytetracycline), not the epimeric form, and thus Pfizer should have expected it to perform better.[19] The McCormick compound, on the other hand, had an opposite configuration at the 6-position and, defendants contend, might be *expected* to compare unfavorably with doxycycline.[20]

[19]Thus, according to defendants, Pfizer knew that the fact that prior art epimers showed a pattern of lower antibacterial activity than their conventional counterparts did not support the argument that doxycycline's higher activity was unexpected. For, although Pfizer referred to doxycycline as having an "epimeric" configuration, defendants contend that Pfizer knew doxycycline was in no way analogous to prior art epimers since doxycycline has a configuration comparable to, rather than opposite, that of the conventional tetracycline antibiotics having higher activity.

[20]Pfizer's diagrams illustrate the so-called "normal" 6-position form of oxytetracycline and doxycycline by a dotted line

(This footnote is continued on next page)

Pfizer's response, however, is that its label "conventional" when applied to a chemical structure was intended to refer only to a member of an epimer pair as first-discovered, and the prefix "epi" or "epimer" to the member discovered second. Pfizer contends it did not intend the word to imply that doxycycline had a "normal" or "natural" configuration in an absolute sense or to compare it with the "natural" process of making oxytetracycline, from which the McCormick and doxycycline compounds are derived "synthetically."[21]

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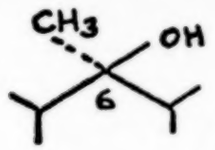
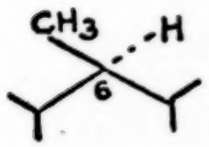
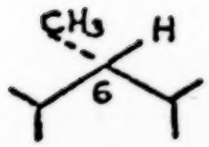
indicating the methyl group (CH_3) as pointing "down." The epimeric or opposite form of the McCormick compound is shown by a solid line indicating CH_3 in the "up" position:



oxytetracycline



McCormick compound



doxycycline

[21]At one point in the patent prosecution, the examiner referred to the 6-methyl group of doxycycline as having an orientation *opposite* that of the fermentation produced compounds. Pfizer contends that it immediately corrected the examiner by explaining that doxycycline has an orientation the *same* as that of the fermentation produced tetracyclines. The examiner accepted Pfizer's correction and has filed affidavits explaining his understanding of this and other issues in the instant proceeding.

The District Court concluded that Pfizer's responses to rejections by the patent examiners, who eventually allowed the doxycycline patent, were deliberate misrepresentations using intentionally confusing language to draw the false analogy and conceal the fact that tetracycline has a 6-position structure similar to the "natural" fermentation produced tetracyclines such as oxytetracycline. Pfizer denies any intent to mislead or confuse the examiner. Again, we believe genuine issues of material fact are present, concerning but not limited to, Pfizer's willfulness and the examiner's understanding of technical facts critical to evaluating Pfizer's conduct.

4. *Misrepresentations of Antibacterial Superiority of Doxycycline.*

Pfizer is accused of misconduct in connection with a second argument that it advanced to overcome the examiners' rejection of doxycycline as unpatentable because obvious. Pfizer submitted scientists' affidavits to show that the antibacterial properties of doxycycline were not only superior to those of the McCormick compound but so dramatically superior that they were unexpected to persons skilled in the art. At the same time, however, defendants contend that Pfizer withheld other less favorable or unfavorable test results, and in so doing, Pfizer was guilty of putting its best foot forward, as an advocate, in violation of its duty of candor to the Patent Office.

Pfizer responds that doxycycline is vastly superior to the McCormick compound in antibacterial activity against most organisms both *in vitro* (in test tubes) and *in vivo* (in experiments on animals). However, in Pfizer's experiments doxycycline proved to be inactive *in vivo* against an organism known as Staph 400.

Pfizer did not report this shortcoming of doxycycline against Staph 400 *in vivo* to the Patent Office, but did report favorable data for doxycycline against Staph 400 *in vitro*. Pfizer's explanation for doing so is that no comparable data revealing the McCormick compound's activity against Staph 400 *in vivo* were available and it contends that, in granting the patent, the examiner did not assume that doxycycline had activity against Staph 400 *in vivo*. Pfizer also has an explanation for a second alleged misrepresentation relating to antibacterial activity defendants accuse it of perpetrating—Pfizer's failure to report its 1964 test results that, defendants contend, reveal a less dramatic contrast between doxycycline and the McCormick compound than that indicated by the 1962 test results Pfizer previously submitted to the examiners. Pfizer contends that the 1964 test results need not have been submitted because they were not inconsistent with the 1962 results, but were within the range of variation to be expected from tests in different laboratory conditions.

Again, we believe the issues of fact joined by these contrasting contentions are genuine and material to defendants' claim of fraud and inequitable conduct. The District Court was unjustified in determining summarily the facts necessary to conclude that Pfizer's argument by analogy and nondisclosure of test data amounted to "deliberate concealment, * * * withholding * * * and misrepresentation" to invoke the unclean hands defense and refuse to enforce the patent.

4. *Failure to Disclose Beliefs Concerning Coproduction of Doxycycline.*

Pfizer is also accused of misconduct in delaying disclosure of its early belief that doxycycline had been

coproduced in trace amounts by Drs. Stephens and McCormick independently in their work on the McCormick compound during the late 1950's.[22] This nondisclosure, according to defendants, deprived the Patent Office for three years of information bearing upon the patent issues of "novelty" under 35 U.S.C. § 103 and erroneous claims of inventorship that may have justified striking the application under the Patent Office rules.[23]

Pfizer responds that although it originally believed trace amounts of doxycycline were coproduced in prior research in the 1950's, overwhelming evidence developed since April, 1962, reveals that no coproduction occurred in the prior processes. During prosecution of the doxycycline application, Pfizer investigated the possibility of prior coproduction and, it contends, in July, 1964, and February, 1965, presented the results to the examiners and summarized the matter in the file

[22]In 1958 and 1959, Drs. Stephens and Conover of Pfizer filed two patent applications describing their own hydrogenolysis process stating that the process produced another compound "thought to be" what is now called doxycycline. Defendants contend that Dr. Stephens further believed that Dr. McCormick's Belgian patented process would also have coproduced doxycycline. However, in its 1961 doxycycline patent application, Pfizer did not disclose these beliefs of possible coproduction but claimed that doxycycline had been invented jointly by Drs. Blackwood, Stephens, Rennhard and Beereboom with a process different from that used before by Drs. Stephens, Conover and McCormick.

[23]Patent Office Rule 56, 37 C.F.R. § 1.56 (1961), provides that any application filed fraudulently "or in connection with which any fraud is practiced or attempted" may be stricken from the files. In their oath of invention, dated May 2, 1961, Dr. Stephens and three other inventors swear that they "believe" they "are the original, first and joint inventors" of the claimed tetracycline derivatives and processes and that they "do not know and do not believe [doxycycline] was ever known or used before [their] invention thereof or patented or described in any printed publication in any country before."

wrapper. The examiners thereafter declined Pfizer's offer to produce more records and Pfizer employees for examination, as the examiners were of the view that the absence of prior art suggestion of coproduction rendered the matter immaterial to patentability. Pfizer's patent counsel, Mr. Oglesby, contends that before he drafted the doxycycline application he concluded that earlier beliefs held by Pfizer scientists that trace coproduction had occurred were of no legal significance for the reason that the four named inventors were the men whose research had led to isolation and identification of doxycycline and determination of its proper utility. Pfizer contends, therefore, that Dr. Stephens executed the inventor's oath in good faith and that, in light of its later explanations to the examiners, omission of the suggestions of coproduction from the 1961 application was not fraudulent or inequitable.

The District Court concluded that Pfizer had deliberately withheld Dr. Stephens' belief and unfavorable test data relating to coproduction and that Pfizer's offers of additional information were insufficient to remedy its prior inequitable conduct. Again, however, we are of the view that these conclusions resolve genuine issues of material fact against Pfizer, not appropriate by summary judgment. At the least, Pfizer's willfulness must be determined after full presentation of evidence by all parties in a plenary trial.

5. *Concealment of Unsuccessful Efforts to Carry Out Processes Claimed in the Patent.*

The final acts of misconduct before the Patent Office charged against Pfizer are its alleged misrepresentations concealing unsuccessful efforts to carry out two of

the many chemical processes claimed in the patent. The first is the statement in Claim 1 of the patent that the noble metal Ruthenium is a "preferred" and "entirely operative" catalyst for producing doxycycline by hydrogenolysis. The second is Pfizer's implicit representation that the process described in Example 35 of the patent, for making a doxycycline-related compound called 7-chloro-doxycycline, is operative. Defendants contend that until the issuance of the patent in 1965, Pfizer had failed in every experimental attempt to use the processes, concealing its failures from the Patent Office, and that but for the concealment, the patents on these two processes would not have issued.[24]

The District Court concluded that Pfizer was unable to carry out the claimed processes and that its failure to disclose its inability was inequitable. Pfizer responds that the documents upon which the District Court relied in so concluding actually report Pfizer's *successful* use of Ruthenium and that throughout the prosecution Pfizer had evidence that both processes were operable. Thus, Pfizer insists, technical issues are present requiring expert interpretation of scientific records. Further, according to Examiner Adams' 1975 affidavits, he was not interested in Pfizer's unsuccessful experiments as long as Pfizer believed the processes were operable. Adams stated he would have allowed the

[24]Affidavits were submitted by Pfizer scientists claiming that the processes are operative, but the defendants discount them for failure to cite actual test results. Defendants also challenge Pfizer's offer of later-developed successful test data because not raised below and not relevant to Pfizer's inequitable concealment from the Patent Office years before. Defendants also note that Examiner Adams, in his affidavit of February, 1975, stated that he would have disallowed patents on the processes had he been informed of conclusive scientific evidence that they are inoperable.

patent to issue unless he were shown conclusive scientific evidence of inoperability and no such evidence was presented.[25]

Our review of the record reveals unresolved technical issues concerning Pfizer's success with the chemical processes and genuine issues of material fact as to Pfizer's willfulness in allegedly concealing lack of success. The District Court erred in summarily finding Pfizer guilty of inequitable conduct before the Patent Office barring enforcement of the patent. We reiterate that summary judgment is not a proper procedure for final determination of factual issues.

III. FRAUD ON THE COURT AND OTHER INEQUITABLE CONDUCT.

The District Court also found Pfizer guilty of making false statements and recklessly disregarding the truth in pretrial proceedings before it, independently justifying refusal to enforce the patent. Pfizer flatly denies any misconduct and complains of the summary manner in which it was found guilty and punished. We have independently reviewed the record and reverse that judgment on the merits. The record of proceedings in the District Court does not reveal sufficient misconduct by Pfizer's agents or counsel to constitute

[25]In his second supplemental affidavit, dated February 24, 1975, Examiner Adams states:

> I was not interested in any and every unsuccessful experiment carried out by Pfizer's research scientists.
>
> * * *
>
> I would have been interested, therefore, only in conclusive scientific evidence that showed that the hydrogenation could not be conducted.
>
> * * *
>
> I do not regard failure to obtain the desired result in several exploratory experiments as conclusive scientific evidence of inoperability.

fraud on the court, reckless disregard for the truth or unclean hands, and the court's findings thereof are clearly erroneous. Fed. R. Civ. P. 52(a). Imposition of the severe sanction was not proper, the factual situation being inadequate for a final disposition.

The facts allegedly concealed were contained in memoranda prepared by the patent counsel who prosecuted Pfizer's doxycycline application. The memoranda concern Pfizer's conduct in connection with disclosure of the Belgian patent to the patent examiners.[26] In the present litigation defendants allege that Pfizer withheld the Belgian patent from the patent examiners to conceal its uncertainty of doxycycline's 5-position stereochemistry, but Pfizer insists that all such information was later disclosed to the examiners in oral interviews not recorded in the file wrapper.[27] In support,

[26]As noted above, Pfizer maintains that when it filed the doxycycline application in May, 1961, it believed the diagrams in the Belgian patent did not depict doxycycline and hence were not *Von Bramer* references required to be cited as prior art. During prosecution, however, in 1963, a Pfizer scientist expressed doubt as to the difference between the 5-position structure of doxycycline and the prior art compounds, and Pfizer resumed experimentation, finally establishing in 1964 that its original belief was correct.

[27]For example, Pfizer contends that in March, 1962, its patent counsel, Mr. Ogelsby, brought the Belgian patent to the examiners' attention and stated that Pfizer believed the diagrams contained therein were in error at the 5- and 6-positions.

Although the defendants contend that under Patent Office Rules 2 and 133, 37 C.F.R. §§ 1.2, 1.133 (1961), all information must be submitted to the Patent Office in writing, it appears that the practice is not so restrictive and that many items are discussed with the patent examiners orally rather than in writing. One commentator has recognized that "the personal appearance of an applicant and/or his * * * agent before the examiner frequently facilitates the disposition of his case." P. Rosenberg, *Patent Law Fundamentals* 221 (1975).

(This footnote is continued on next page)

Pfizer relies upon internal memoranda relating to the interviews contained in the patent prosecution files of its patent counsel. However, due to a special "ground rule" of discovery that evolved in the case in connection with the masters who were appointed to rule on claims of privilege and work product, these memoranda were not produced by Pfizer in the discovery process. Under

The U.S. Patent Office examiner's manual explains the practice under Rules 2 and 133 and distinguishes situations in which an oral agreement is reached between the attorney and the examiner from those in which an interview is had but no agreement is reached. In the former situation, a formal memorandum of the interview, signed by both, must later be filed by the applicant; but in the latter situations the *examiner* is expected to place in the file an informal memorandum that should later be "removed from the file if and when the case is passed to issue." U.S. Patent Office, *Manual of Patent Examining Procedure* § 713.04 (3d ed. 1961), *as amended* (1970), *reprinted in,* A. Deller, *Walker on Patents* ch. XVI, appendix at 383 (2d ed. 1972). The Supreme Court has recognized that "all facts concerning * * * [possible fraud or inequitableness should] be submitted *formally or informally* to the Patent Office" to safeguard the public interest in proper patent administration. *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.,* supra at 818. (Emphasis added.)

We will not attempt in this opinion to resolve the impact of the above Patent Office rules and procedures on evidentiary rulings in district court infringement litigation. The District Court made no precise ruling on that issue and if the court's decision rests upon enforcement of the Patent Office rules, we would be confronted with an additional issue which we do not perceive. We express no view of Pfizer's alleged noncompliance with required procedures in the Patent Office or of the effect of such noncompliance, if any, upon Pfizer's right to rely on past oral interviews in its proof with reference to statutory issues of patentability. But quite aside from the admissibility of the evidence as it relates to such statutory issues, we believe evidence of matters brought orally or informally to the attention of the Patent Office is relevant to the issues of fraud and inequitable conduct by the patentee and should be admitted in the instant litigation as to these issues, if sufficiently reliable, regardless of the patentee's alleged noncompliance with Patent Office rules and procedures governing proceedings determining statutory patentability. The District Court should resolve these separate issues on remand and reconsider its prior estoppel of Pfizer from relying upon evidence of oral Patent Office interviews.

the rule, internal documents remaining in the files of the law firm that created them need not be produced to the masters for determination of privilege claims so long as the documents were attorney work product and were never disclosed to anyone, including the client, outside the firm.[28]

When Pfizer relied upon the undisclosed memoranda in September, 1974, to corroborate its claim that it orally disclosed the Belgian patent and uncertainty of 5-position stereochemistry to the examiners during prosecution, defendant USV moved to compel Pfizer to produce the memoranda and accused it of unlawfully withholding them. Pfizer maintained, as it had previously, that the memoranda were protected under the discovery ground rule as attorney work product that had never been disclosed outside the law firm. However, during January and February, 1975, in hearings on USV's motion, Pfizer's counsel disclosed that the files of its patent counsel containing the memoranda had been loaned to Pfizer early in the litigation. Thus, Pfizer conceded that the memoranda were not covered by the discovery ground rule and the District Court characterized Pfizer's conduct as fraudulent and reckless.

Pfizer responds that its continuing misstatement that the files had not been disclosed outside the firm stemmed from an innocent error of counsel, promptly corrected when discovered on January 28, 1975. Moreover, it

[28]The opposing party seeking such undisclosed documents is required to proceed instead by subpoena duces tecum directed to the law firm in the forum where the firm is located. The rule thus enables the firm to defend the sanctity of its own files. All other documents not covered by the ground rule were to be produced to the masters for consideration of claims of privilege. Both parties could then dispute the masters' rulings as to discoverability of individual documents.

contends that by the time the error was discovered it was no longer significant because all facts pertaining to Pfizer's earlier uncertainty of 5-position stereochemistry had been disclosed to the court and explored by the defendants in other discovery. In fact, copies of the memoranda had been voluntarily submitted to the overburdened masters on October 18, 1974; but as of February, 1975, the masters had not yet screened documents submitted as early as May, 1974. Thus, Pfizer contends, defendants could not have been prejudiced by the delayed disclosure resulting from the error.

Moreover, Pfizer contends, the memoranda are favorable to its position in the litigation in that they confirm that the Belgian patent and Pfizer's uncertainty of 5-position stereochemistry were disclosed to the examiners during prosecution.[29] Thus, Pfizer points out that it had no motive to conceal the memoranda, and on February 3, 1975, it voluntarily waived its privilege and work product claims and delivered them directly to the defendants.

Fraud on the court, though not easily defined, can be characterized as a scheme to interfere with the judicial machinery performing the task of impartial

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[29]For example, a March 12, 1963, memorandum of Dr. Knuth, Associate Director of Patents for Pfizer, produced to defendants on May 13, 1974, states that the Belgian patent and uncertainty of 5-position stereochemistry (raised by a publication of a Pfizer consultant, Prof. Muxfeldt, in December 1962) were discussed with Examiner Berg in an interview in the Patent Office on March 5, 1963, and summarizes Pfizer's presentation.

Also, Pfizer had produced its patent files to the masters in 1973, including Pfizer's March 7, 1961, letter to Ogelsby discussing the Belgian patent and revealing Pfizer's pre-application beliefs concerning 5- and 6-position stereochemistry. In June, 1973, the masters ruled the document privileged.

adjudication, as by preventing the opposing party from fairly presenting his case or defense. *Kupferman v. Consolidated Research & Manufacturing Corp.*, 459 F.2d 1072, 1078 (2d Cir. 1972); *England v. Doyle*, 281 F.2d 304, 309 (9th Cir. 1960); *see* Annot., 19 A.L.R. Fed. 761 (1974). A finding of fraud on the court is justified only by the most egregious misconduct directed to the court itself, such as bribery of a judge or jury or fabrication of evidence by counsel, *United States v. International Telephone & Telegraph Corp.*, 349 F.Supp. 22, 29 (D.Conn. 1972), *aff'd sub nom. Nader v. United States*, 410 U.S. 919 (1973); 7 J. Moore, *Federal Practice* ¶ 60.33, at 515 (2d ed. 1976), and must be supported by clear, unequivocal and convincing evidence. *Barr Rubber Products Co. v. Sun Rubber Co.*, 425 F.2d 1114, 1120 (2d Cir.), *cert. denied*, 400 U.S. 878 (1970). We have reviewed the record of proceedings in the District Court and we believe the conduct of the accused individuals did not evidence a scheme to improperly influence or impair the court's function, and was not egregious misconduct characterizable as fraud on the court. *Kupferman v. Consolidated Research Manufacturing Corp., supra* at 1081; *cf. Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245-46 (1944) (scheme by patentee to defraud the court by relying upon an article supposedly written by a disinterested author, but actually written and published by patentee); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 243 (1933) (scheme by patentee to suppress evidence by paying witness to remain silent); *Mas v. Coca-Cola Co.*, 163 F.2d 505 (4th Cir. 1947) (scheme by patentee to establish priority of invention in court with forged documents).

Nor does the record support the District Court's alternative finding that Pfizer's conduct in the pretrial proceedings, even if not a fraud on the court, amounted to unclean hands, justifying refusal to enforce the patent. Such extreme sanction, predicated upon the unclean hands doctrine, also requires a showing of fault, willfulness or bad faith more substantial than presented here. *See Societe Internationale v. Rogers,* 357 U.S. 197, 212 (1958); *General Dynamics Corp. v. Selb Manufacturing Co.,* 481 F.2d 1204, 1211, 1214 (8th Cir. 1973), *cert. denied,* 414 U.S. 1162 (1974).

The root of confusion that triggered the court's drastic action was but a single misrepresentation that the memoranda had not been released by the law firm, repeated by many individuals on Pfizer's behalf until discovered by attorney Ogelsby to be erroneous on January 28, 1975.[30] Thereafter, on January 31, 1975, counsel for Pfizer promptly brought the error to the court's attention. Pfizer's conduct had the effect of impeding discovery and prolonging this already protracted litiga-

[30]We have reviewed the record relating to four additional items asserted to have been part of Pfizer's scheme and hold them to be inadequate even in combination to justify a finding of fraud on the court or inequitable conduct to trigger the severe sanction. These are: (1) an argument by Pfizer's counsel, Mr. Cooper, that 5-position (as opposed to 6-position) stereochemistry was always irrelevant to patentability of doxycycline, found by the court to be a deliberate misrepresentation; (2) an affidavit of Mr. Ogelsby, dated July 30, 1974, found by the court to have contained the same misrepresentation; (3) Mr. Ogelsby's preparation for and testimony during his March 5, 1974, deposition, found by the court to have been deliberately incomplete and misleading; and (4) a notation on a draft patent application contained in Ogelsby's files, found by the court to indicate that some of Ogelsby's files were provided to Pfizer in February, 1974, apparently suggesting that Ogelsby had knowledge thereof prior to his March, 1974, deposition.

Moreover, in our view, Pfizer has a reasonable explanation relating to each of these four allegations of misconduct.

tion and is not to be viewed lightly, but it did not justify the severe sanction imposed. Though Pfizer's failure to investigate the handling of the internal memoranda at an earlier date was a serious error in judgment, the conduct of the accused individuals acting on its behalf was not fraudulent or reckless, nor indicative of a scheme to conceal material facts. The facts so concealed were basically supportive of Pfizer's contentions.

The basic issues in this case are the validity and enforceability of the patent alleged to have been infringed. An infringement defendant in complex litigation should not be permitted to sidestep these main issues by nit-picking the patent file in every minute respect with the effect of trying the patentee personally, rather than the patent. A patentee's oversights are easily magnified out of proportion by one accused of infringement seeking to escape the reach of the patent by hostilely combing the inventor's files in liberal pretrial discovery proceedings. Unjustified damage to professional and social reputations can result, as here, without fostering any corresponding public benefit in the form of inhibiting future improvident grants of patent monopolies.

IV. RELIEF.

Finally, Pfizer requests that we remand this action to the Central District of California for completion of pretrial proceedings and trial. It argues that the District Judge herein has made factual determinations that he may not be able to retract, that IRC's antitrust action against Pfizer has now been settled, leaving no other litigation involving IRC and USV before this District Judge, and that no other judge in the

District of Minnesota is familiar with the instant case. We deny Pfizer's request. The case was placed by the Judicial Panel on Multidistrict Litigation in the hands of the District Court for pretrial proceedings. When ready for trial, the case will take its normal course under the direction of the Panel without direction from this court.[31]

In conclusion, it should be understood that we are not attempting to resolve disputed issues of fact or pass upon the serious charges made by the defendants in regard to the manner in which the patent application was prosecuted by Pfizer before the Patent Office. Nor do we attempt any resolution of the statutory issues of validity or equitable issues of enforceability of the patent raised by the defendants. All of these issues remain yet to be resolved in a plenary trial. We, however, do hold that according to the record before us, no fraud was practiced on the District Court in these pretrial proceedings.

The judgment of the District Court is reversed and the case remanded for completion of pretrial proceedings consistent with this opinion, and a plenary trial in a district to be selected by the Judicial Panel on Multidistrict Litigation.

Costs are assessed against defendants.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS,
EIGHTH CIRCUIT

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[31]Orders of the Panel are reviewable only by extraordinary writ. 28 U.S.C. § 1407(e). Pfizer, of course, is free to request an order of remand from the Panel itself. Rules of Procedure of the Judicial Panel on Multidist. Lit. 11(c) and (d) (1975).

Paragraph 8 of Examiner Adams' Affidavit (February 3, 1975).

8. At all times during the prosecution of the '146 application, I would also have been interested in and considered material, any scientific evidence that Pfizer had been unable to successfully employ ruthenium, one of the noble metal catalysts disclosed in Said Application, to catalyze the hydrogenation of a 6-methylenetetracycline compound (as depicted in claim 1 of the '149 Patent) to produce the corresponding claimed compounds. Had I been informed that such was the fact, I would have rejected at least claim 1 of the '146 application as failing to comply with 35 U.S.C. 112 in claiming the hydrogenation process in the presence of any noble metal catalyst.

Blackwood, et al. Affidavit (March 27, 1975).

State of Connecticut, County of New London—SS.:

WE, ROBERT K. BLACKWOOD, JOHN J. BEEREBOOM, HANS H. RENNHARD AND CHARLES R. STEPHENS, JR., being duly sworn, say:

1. We are the joint inventors listed in U.S. Patent 3,200,149.

2. At the time we executed the Oath and Supplemental Oath with respect to the application for U.S. 3,200,149, we believed the matters attested to to be true.

3. We believed during the prosecution of the application, and believe now, that ruthenium is operative in the process disclosed in the patent.

4. We believed during the prosecution of the application, and believe now, that 7-chloro-6-epi-6-deoxy-5-oxytetracycline can be made by the process disclosed in the patent.

Dated March 27, 1975.

/s/ Robert K. Blackwood
Robert K. Blackwood
/s/ John J. Beereboom
John J. Beereboom
/s/ Hans H. Rennhard
Hans H. Rennhard
/s/ Charles R. Stephens, Jr.
Charles R. Stephens, Jr.

Sworn to and subscribed before me this 27th day of March, 1975.

/s/ Patricia L. Kelbaugh
Notary Public
My Commission Expires Mar. 31, 1975

Blackwood—Affidavit (April 9, 1975).

State of New York, County of New York—ss:

I, ROBERT K. BLACKWOOD, being duly sworn, say:

1. I am one of the joint inventors listed in U.S. Patent 3,200,149.

2. Before May 1961, doxycycline had been produced using rhodium as a catalyst, and I knew from published literature that ruthenium catalyzed double-bond hydrogenation just as did rhodium. My knowledge as an organic chemist would lead me to believe that ruthenium would be operative as a catalyst in producing doxycycline, notwithstanding inconclusive preliminary experiments before the application was filed. I would attribute the inconclusive individual experiments to unsuitable conditions rather than to any inherent inoperability of ruthenium. I believed at the time the application was filed that ruthenium was operable as a catalyst and, in fact, I have made doxycycline using ruthenium as a catalyst as taught by the patent.

3. Before May 1961, doxycycline had been produced by hydrogenating a 6-methylene tetracycline parent, and my knowledge as an organic chemist would lead me to believe that 7-chloro doxycycline could be produced by hydrogenating a 7-chloro-6-methylene tetracycline parent, notwithstanding inconclusive preliminary experiments before the application was filed. I would attribute the inconclusive individual experiments to unsuitable conditions rather than to any inherent inoperability of the invention in producing 7-chloro

doxycycline. I believed at the time the application was filed that 7-chloro doxycycline could be produced by the process of the patent and, in fact, Rachelle has represented in its patent (Exh. A—#3,795,707) that it has been done by our process. The title of Example 6 in the Rachelle patent concedes the fact that it makes "7-chloro-∝-6-deoxy-5-oxytetracycline from 7-chloro-6-methylene-5-oxytetracycline", just as Examples VI B and XXXV of our patent teach.

Dated: April 9, 1975

/s/ Robert K. Blackwood
Robert K. Blackwood

Sworn to and subscribed before me this 9th day of April, 1975.

/s/ Doris J. Russert
Notary Public

Paragraph 8 of Examiner Adams Affidavit (February 24, 1975).

8. The statements made in Paragraph 8 of my Supplemental Affidavit are based on the hypothetical assumption that there was scientific evidence that ruthenium was inoperative, i.e., that it would not catalyze the hydrogenation process of the patent. By "scientific evidence" I mean "reliable" or "conclusive" scientific evidence as explained in Paragraph 7 herein. I do not regard failure to obtain the desired result in several exploratory experiments as conclusive scientific evidence of inoperability. I recognized during prosecution of the Blackwood et al application and I recognize now that particular research experiments falling within the scope of a claimed invention may be unsuccessful without that invention being inoperative and the claims invalid. I also recognized during prosecution, and I recognize now, that the failure of some experiments does not preclude inventors from properly claiming an invention that broadly encompasses such experiments because the reasons for failure may be apparent upon investigation. For example, investigation may reveal that the experiments were carried out by incompetent or inexperienced technicians or that the specific circumstances or conditions employed led to failure, e.g., use of a relatively inactive catalyst sample, inadequate time, or choice of particular reaction medium or conditions. Therefore, I would not regard such experiments as conclusive scientific evidence of inoperability, i.e., that the process cannot be successfully carried out without the exercise of more than ordinary skill in the art. Moreover, it was not then, and is not now, my understanding of patent law that, in the light of experimental failure, successful experiments had to be

conducted before claims encompassing the experimental failures could be filed.

Paragraph 19 of Stephens Affidavit (March 27, 1975).

19. I testified in response to questions at my deposition on February 21, 1975 as follows:

> "The hydrogenations and catalysts are very sensitive and variable. For example, many batches of catalysts of the exact same chemical composition can vary dramatically in their activity, like a catalyst that has been sitting on a shelf for a—in a certain environment can be inactivated, and a certain chemist can get that particular bottle of catalyst and do a reaction and say nothing happened or that something weird happened, and then somebody can repeat that by preparing a more active catalyst, or more consistent catalyst, and get quite a different result.
>
> "So, taking everything in preliminary catalytic hydrogenations, you know, as being absolute, it's very hard. There are many, many factors."

I believe that testimony to be true.

Last Paragraph of Pfizer Exhibit 35 M (December 20, 1960).

Palladium and ruthenium were also tried as catalysts but effected little hydrogenation. Platinum can be used but gives more degradation products of the apaterramycin type. Hydrogenation in basic medium also gave many degradation products. Addition of acetic acid did not offer any advantages. Reduction at normal pressure is very slow. The hydrogenation at high pressure is under investigation.